

## Independent Group Advising on the Release of Data (IGARD)

### Minutes of meeting held 20 December 2018

**Members:** Sarah Baalham, Anomika Bedi, Kirsty Irvine (Chair),

**In attendance:** Louise Dunn, Giles Foster, James Humphries-Hart, Dickie Langley, Karen Myers, Vicki Williams.

**Apologies:** Joanne Bailey, Nicola Fear, Eve Sariyannidou.

**Observers:** Maria Clark, Anna Duggan (Items 2.5 - 2.8)

1	<p><b>Declaration of interests:</b></p> <p>Kirsty Irvine noted professional links to the Royal College of Obstetricians and Gynaecologists (NIC-44356-Y8N6R) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The outcomes of the 13<sup>th</sup> December 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting.</p> <p>The minutes of the 13<sup>th</sup> 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.</p> <p><b>Out of committee recommendations</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<b>Data applications</b>
2.1	<p><u>Maternity Services Data Set Briefing Paper (Presenter: Giles Foster)</u></p> <p>This briefing was to inform IGARD of the onboarding to the Data Access Request Service (DARS) of the Maternity Services Dataset (MSDS).</p> <p>The MSDS dataset was mandated for central flow to NHS Digital from 1<sup>st</sup> April 2015 for all providers of NHS funded maternity services, as set out by the Health and Social Care Act 2012.</p> <p>The dataset was developed to help achieve better outcomes of care for mothers, babies and children. The data collected include mother's demographics, booking appointments, admissions and re-admissions, screening tests, labour and delivery along with baby's demographics, diagnoses and screening tests.</p> <p>The current version of the dataset, MSDS v1.5 is due to be succeeded in April 2019 by MSDSv2.0. The new dataset builds on the existing v1.5 data by introduces a new structure and content, including clinical terminology, in order to meet current clinical practice and incorporate new requirements from policy developments.</p> <p>IGARD welcomed the briefing note and requested that a copy of the Data Protection Impact Assessment (DPIA) be provided and to provide a link to the Direction.</p> <p><b>ACTION:</b> Moving forward DPIA's, where available, should be provided with all briefing notes to IGARD.</p>
2.2	<p><u>Royal College of Obstetricians and Gynaecologists: NMPA: ONS-PDS-HES-MSDS-MIS-Mental Health and ONS-PDS-PEDWNCCHDS-Mlds Linked Datasets (Presenter: Louise Dunn) NIC-44356-Y8N6R</u></p>

**Application:** This was an amendment, extension and renewal application for pseudonymised Hospital Episode Statistics (HES) data, Mental Health Minimum Dataset (MHMDS), Civil Registrations data, Medical Research Information Service (MRIS), Mental Health Services Dataset (MHSDS) and identifiable Maternity Service Dataset (MSDS). The purpose is for the Healthcare Quality Improvement Partnership (HQIP), National Clinical Audit and Patients Outcomes Programme's National Maternity and Perinatal Audit (NMPA) to deliver a clinically meaningful and methodologically robust audit of NHS maternity services to enable decision making and support the improvement of quality of care.

**Discussion:** IGARD noted that the Healthcare Quality Improvement Partnership (HQIP) had not provided adequate evidence to substantiate that public task is the appropriate legal basis.

IGARD noted that RedCentric PLC 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.

IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at the latest within one month".

IGARD queried the first special condition in section 6 (Special Conditions) *"In light of no confirmation of best practice controls for Red Centric of ISO 27002, 2017, 2018 that that client has undertaken a risk assessment and will accept the risk should any incident occur."* and were advised by NHS Digital that the Security Advisor had requested that this be included. IGARD asked that this be amended to clarify that it meets the NHS Digital Security Advisors requirements.

IGARD noted that section 5(b) (Processing Activities) states that only the Royal College of Obstetricians and Gynaecologists will access the data and asked that this be replicated as a special condition in section 6.

IGARD noted the clause in section 6 *"All Intellectual Property Rights in any guidance, specifications, instructions, toolkits, plans, data, drawings, databases, patents, patterns, models, design or other material, furnished or made available to the Health and Social Care Information Centre as part of the application of this request remains vested solely in HQIP. This IPR is in turn vested to NHS England through HQIP's headline contract with them."* and asked that NHS Digital review and confirm that the clause is suitable and appropriate.

IGARD noted the legal references in section 3(b) (Additional Data Access Requested) and asked that this be amended to include s251 and the NHS Service Regulations 2003.

IGARD suggested that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient / stakeholder engagement.

**Outcome:** Unable to recommend for approval due to the outstanding issue relating to the legal basis:

1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis.

IGARD made a positive statement of advice and requested the following amendments:

1. IGARD noted that RedCentric PLC 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.

	<ol style="list-style-type: none"> <li>To update section 4 with the standard wording “All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the 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”.</li> <li>To amend the first special condition in section 6 to clarify that it meets the NHS Digital Security Advisors requirements.</li> <li>To include a special condition in section 6 that only the Royal College of Obstetricians and Gynaecologists will access the data.</li> <li>NHS Digital to review and confirm that the IPR clause is suitable and appropriate.</li> <li>To amend the legal references in section 3(b) to include s251 and the NHS Service Regulations 2003.</li> <li>To provide further details of pathways of dissemination of the outputs including any specific examples of public / patient / stakeholder engagement.</li> </ol>
2.3	<p><u>University of Leeds: Is Quality of life a matter of distance? A study investigating the relationship between centralising health services and health inequalities for patients with rheumatoid arthritis and Osteoarthritis (Presenter: Louise Dunn) NIC-337151-T2S2K</u></p> <p><b>Application:</b> This was an extension application for pseudonymised Hospital Episode Statistics (HES) data and Patient Reported Outcome Measures (PROMs) data for a study looking to answer the research question and test the study’s hypothesis that; “Centralising hospital treatment will disproportionately affect those patients who live at a greater distance from the healthcare they need to attend and / or those that have limited transport accessibility resulting in impact on health inequalities”.</p> <p>NHS Digital confirmed that previous identifiable data held by the University of Leeds in relation to this application has now been destroyed.</p> <p><b>Discussion:</b> IGARD noted that section 4 (Privacy Notice) was incorrect as the University of Leeds already hold the data and asked that the following be removed “...<i>within a reasonable period after obtaining the personal data, but at least within 1 month.</i>”</p> <p><b>Outcome:</b> recommendation to approve</p> <ol style="list-style-type: none"> <li>To amend section 4 to delete the text following “GDPR requirements”.</li> </ol>
2.4	<p><u>University of York (Presenter: Louise Dunn) NIC-68774-M1W6Q</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) data and Civil Registrations data. The project aims to answer whether modern day cardiac rehabilitation as delivered in routine practice across the UK remains beneficial for patients. The project will achieve this aim by investigating whether mortality, re-admission and reoccurrence significantly differs between cardiac rehabilitation attenders versus non-attenders. The results of this project will address an important issue in terms of future commissioning in the NHS for cardiac care i.e. whether cardiac rehabilitation in its current format should continue to be funded. With over 80,000 patients in the UK accessing cardiac rehabilitation services each year the findings of this project could have a profound impact on future patient care.</p> <p><b>Discussion:</b> IGARD queried the role of the NHS Digital Clinical Audit Team as referenced in the application and asked for further clarity in the abstract on the role of the NHS Digital Clinical Audit Team and the platform service they are providing.</p>

	<p>IGARD queried if the University of Leeds and the Farr Institute would be accessing the data and were advised by NHS Digital that there would not. IGARD asked that a special condition be included in section 6 (Special Conditions) stating this.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To provide further clarity in the abstract on the role of the NHS Digital Clinical Audit Team and the platform service they are providing.</li> <li>2. To include a special condition that no record level data will be accessed by the University of Leeds or Farr Institute.</li> </ol>
2.5	<p><u>University of Warwick: Modelling the Frailty Patient Pathway (Presenter: Rachel Farrand)</u> <u>NIC-32537-Y2H2L</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a research project to understand the variation in the care of older patients attending hospital and the support the modelling of in-hospital patient pathways for older patients with complex needs.</p> <p><b>Discussion:</b> The application was been previously considered on the 11<sup>th</sup> October 2018 when IGARD had deferred making a recommendation pending; appropriate additional contractual clauses which are effective to make the University of Warwick fully and solely responsible for any breaches of the DSA by the PhD student and include an undertaking that NHS Digital will report any data breaches to the ICO; to clarify that SaTH are joint DC and remove reference to contradictory statements that suggest otherwise; to remove reference to a “sole Data Controller” within the application; to provide further justification within section 5 for the receipt of national data; 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 public task for Foundation Trusts; to remove reference to cancer waiting time in the abstract, since it is not relevant to the application; to specifically state within section 5 that the individuals accessing the data are the PhD student and supervisor; to confirm the start date of the student’s PhD and at what stage of the PhD they are at and why they are requiring the data now; to provide further details of pathways of dissemination of the outputs including any specific examples of public / patient engagement and dissemination plans; to briefly explain what the Acute Frailty Network is within section 5 of the application; to remove the sentence in Section 7 stating that ethics approval is required, since it is not required for the application; to update the abstract with a fair processing notice review for all data controllers.</p> <p>NHS Digital advised that section 5(a) (Objective for Processing) had been updated to specifically state that the individuals accessing the data are the PhD student and supervisor and that this also needed to be replicated in section 5(b) (Processing Activities).</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the project and the interesting work being undertaken. IGARD also noted and commended the data minimisation efforts undertaken by the applicant.</p> <p>IGARD noted that the application had been updated to reflect most of the comments previously made.</p> <p>IGARD noted previous point 5 had not been fully addressed and 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 GDPR be updated to reflect recent discussions between NHS Digital and IGARD</p>

	<p>including, but not limited to, reference to section 43(5) NHS Act 2006 in relation to the legal basis for Foundation Trusts.</p> <p>IGARD noted the special condition in section 6 (Special Conditions) in relation to the PhD student and asked that this be amended to state for clarity that “NHS Digital draws to the attention of the University of Warwick that NHS Digital regards the University of Warwick as being responsible for the actions and omissions of the PhD student.”</p> <p>IGARD noted that previous point 7 had not been fully addressed and suggested that section 5(b) (Processing Activities) be updated to specifically state that the individuals accessing the data were the PhD study and supervisor, as already noted in section 5(a) (Objective for Processing).</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. To amend the special condition in section 6 to state that “NHS Digital draws to the attention of the University of Warwick that NHS Digital regards the University of Warwick as being responsible for the actions and omissions of the PhD student.”</li> <li>3. To update section 5(b) to specifically state that the individuals accessing the data are the PhD student and supervisor as noted in section 5(a).</li> </ol>
2.6	<p><u>McKinsey &amp; Company Inc: Hospice UK: Hospice-led innovations for end of life care (HOLISTIC) (Presenter: Rachel Farrand) NIC-90989-D6T1T</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for a service evaluation on the effectiveness of end of life care programmes in moving patients out of hospitals at the end of their lives and into other locations of care, such as their homes and hospices, and in their ability to prevent avoidable hospital admissions for these patients. This is a joint evaluation and the organisations involved are NHS England and Hospice UK who are leading the service evaluation, McKinsey and Company Inc who are the contracted data processor and St Giles Medical who are performing qualitative data collection and analysis.</p> <p>The application was been previously considered on the 8<sup>th</sup> November 2018 when IGARD had deferred making a recommendation pending; to confirm the lawful basis for receipt of, processing of and dissemination of the data, and in particular at what point the details of living individuals (if any) are being processed and at what point data relating to deceased individuals is being processed, and the legal basis to be updated, as may be necessary, to reflect the status of the individual’s data being processed; to clarify within section 5 the appropriate contractual arrangements between NHS England (data controller) and McKinsey &amp; Co Inc (data processor); to include a special condition clarifying that the data will only be processed in England and Wales; to provide clarification with regard to who the data subjects are, how the cohorts are formed and selected, and in particular for cohort 4, the size and ratios used; to clarify within section 5 what is meant by the reference “each cohort” within the description for cohort 3; pending the analysis under the lawful basis, Hospice UK to provide a fair processing notice that is compliant with the notice requirements under the GDPR, including but not limited to reference to the data flows and personal data.</p> <p><b>Application:</b> IGARD noted that the application had been updated to reflect all of the comments previously made and thanked the presenter for the work that had gone in to clarifying the various cohorts and presenting in language suitable for a lay reader in section 5 of the application.</p>

	<p>IGARD noted in section 5(a) (Objective for Processing) that McKinsey and Company Inc is undertaking the role on a pro-bono (unpaid) basis and asked that this also be noted in section 5(e) ("Is the purpose of this application in anyway commercial?").</p> <p>IGARD noted the following in section 5(b) (Processing Activities) <i>"By signing the Data Sharing Agreement, the Data Controller confirms that the Data Processors listed within this agreement have each: Confirmed that they understand their roles and responsibilities on behalf of the Data Controller as defined within the Data Sharing Agreement. Confirmed that the Processing Activities described within the Data Sharing Agreement are accurate and achievable in terms of the particular Data Processors' processing."</i> and asked that this is also replicated as a special condition in section 6 (Special Conditions).</p> <p>IGARD queried if anyone other than McKinsey &amp; Company Inc would be accessing the data and were advised by NHS Digital that no one else would access the data. IGARD asked that a special condition be included in section 6 (Special Conditions) stating this.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To note within section 5(e) that McKinsey and Company Inc is undertaking this work on a pro bono basis.</li> <li>2. To replicate the following as a special condition <i>"By signing the Data Sharing Agreement, the Data Controller confirms that the Data Processors listed within this agreement have each: Confirmed that they understand their roles and responsibilities on behalf of the Data Controller as defined within the Data Sharing Agreement. Confirmed that the Processing Activities described within the Data Sharing Agreement are accurate and achievable in terms of the particular Data Processors' processing."</i></li> <li>3. To insert a special condition stating that only McKinsey &amp; Company Inc will access the data.</li> </ol>
2.7	<p><u>London School of Hygiene and Tropical Medicine: Infectious disease triggers of chronic disease exacerbations (Presenter: Rachel Farrand) NIC-145260-G4Y0G</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a study examining the timing of hospitalisations for three major chronic diseases, asthma, chronic obstructive pulmonary disease (COPD) and coronary heart disease, to detect associations between known viral and environmental triggers for these conditions.</p> <p>NHS Digital advised that section 5(c) (Specific Outputs Expected) refers to ONS terms and conditions and this would need to be removed since it was not relevant to this application.</p> <p><b>Discussion:</b> IGARD noted the work undertaken by the applicant and NHS Digital, and extended their thanks.</p> <p>IGARD queried if the data requested was for the entire population or just for children, NHS Digital advised that the entire population was of interest not just children and IGARD asked that section 5(a) (Objective for Processing) was amended to reflect this statement.</p> <p>IGARD queried if anyone other than the London School of Hygiene and Tropical Medicine would be accessing the record level data and were advised by NHS Digital that no one else would access. IGARD asked that a special condition be included in section 6 (Special Conditions) stating this</p> <p>IGARD noted reference to HDRUK (Health Data Research UK) in the application and asked that the application be amended to reference the full name of the organisation and a brief description of who they were.</p>

	<p>IGARD queried if funding was still in place and were advised by NHS Digital that it was, IGARD asked that section 1(a) (Abstract) be updated to confirm that NHS Digital are satisfied that funding was in place.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To remove reference to ONS terms and conditions in section 5(c) since it is not relevant to this application.</li> <li>2. To amend section 5(a) to make clear that the entire population is of interest for this study, not just children.</li> <li>3. To include a special condition in section 6 confirming that only the London School of Hygiene and Tropical Medicine will be accessing the record level data.</li> <li>4. To amend reference to HDRUK within the application to state the full name of the organisation and a brief description.</li> <li>5. To confirm within the abstract that NHS Digital are satisfied that funding is in place.</li> </ol>
2.8	<p><u>Newcastle University: MR1032 - The NEWCASTLE 85+ STUDY: BIOLOGICAL, CLINICAL &amp; PSYCHOLOGICAL FACTORS ASSOCIATED WITH HEALTHY AGEING (Presenter: Rachel Farrand) NIC-148471-FR43L</u></p> <p><b>Application:</b> This was a new application for identifiable Medical Research Information Service (MRIS) data for a study to determine the full spectrum of health within an inception cohort of 85 year olds, irrespective of health status, to establish the distribution and variability of a broad range of health measures within this age group; and to examine in unprecedented detail, the health trajectories and outcomes as the cohort aged and the associations with underlying biological, medical and social factors.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the study and were supportive of the valuable work being undertaken. No further comments were raised by IGARD.</p> <p><b>Outcome:</b> recommendation to approve</p>
2.9	<p><u>195 Clinical Commissioning Groups in England: An amendment for 195 CCGs to receive Civil Registration Data for Deaths and Births (Presenter: James Humphries-Hart) NIC-256757-X1M7X</u></p> <p><b>Application:</b> This was an amendment application 195 Clinical Commissioning Groups (CCGs) to receive Civil Registration Data for Deaths and Births to maintain patient health records on NHS systems in relation to births and deaths.</p> <p><b>Discussion:</b> IGARD noted that information had already been provided in the application outlining the processing activities undertaken, however asked if section 5 (Purpose / Methods / Outputs) be updated to also provide further information on the processing activities undertaken.</p> <p>IGARD advised that the abstract be amended to clearly state that for the purposes of presentation to IGARD and administrative ease, the 195 CCGs had been grouped together with the exception of those CCG's that are part of (Sustainability and Transformation Partnership (STP's). However, the application was not a multi-party application with joint Data Controllers but instead an application of individual CCG's with individual NIC numbers, Data Sharing for Commissioners (DSFCs) and Data Sharing Agreements (DSAs) with no linkage of data, with the CCG's being sole Data Controllers.</p> <p><b>Outcome:</b> recommendation to approve</p>

	<p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update section 5 to provide further information on the processing activities undertaken.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. To amend the abstract to clearly state that for the purposes of presentation to IGARD and administrative ease, the 195 CCGs had been grouped together with the exception of those CCG's that are part of STP's. However, the application was not a multi-party application with joint Data Controllers but instead an application of individual CCG's with individual NIC numbers, DSFCs and DSAs with no linkage of data, with the CCG's being sole Data Controllers.</li> </ol>
2.10	<p><u>NHS Wolverhampton CCG: DSfC - NHS Wolverhampton CCG and Wolverhampton City Council - Comm (Presenter: James Humphries-Hart) NIC-218988-L5K0G</u></p> <p><b>Application:</b> This was a new application for pseudonymised Secondary Use Service (SUS) data to provide intelligence to support commissioning of health services. The data will also be used to provide Health and Social Care tools that will support Clinical Commissioning Group and Local Authority in improving integrated working and the delivery of integrated health and social care in order to improve outcomes in ways such as those set out in the Better Care Fund (BCF).</p> <p><b>Discussion:</b> IGARD queried some of the organisations referenced in the application and asked that the abstract and throughout the application be updated to clarify the legal names and trading names of the organisation(s) involved and amend where appropriate.</p> <p>IGARD noted that Equinix LD3 DC (Disaster Recovery) was not listed in section 5(b) (Processing Activities) and asked that this be amended to include them.</p> <p>IGARD noted that section 2(a) (Processing Locations) and section 2(b) (Storage Locations) should be updated to insert "care of" before Equinix LD3 DC (Disaster Recovery).</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To clarify in the abstract and throughout the application the legal names and trading names of the organisations involved and amend where appropriate.</li> <li>2. To amend section 5(b) to include Equinix LD3 DC (Disaster Recovery).</li> <li>3. To update section 2(a) and 2(b) to insert "care of" before Equinix LD3 DC (Disaster Recovery).</li> </ol>
2.11	<p><u>King's College London: Therapeutic Assessment (TA) of Adolescents Presenting with Self Harm versus Standard Psychosocial Assessment and Risk Management. Randomised Controlled Trial 8 Year Follow Up. (Presenter: Dickie Langley) NIC-134027-L9T9J</u></p> <p><b>Application:</b> This was a new application for identifiable Hospital Episode Statistics (HES) and Civil Registrations data to investigate the longer-term outcomes of treatment, engagement and A&amp;E attendance among adolescents accessing South London and Maudsley Children and Adolescent Mental Health Services (CAMHS) who received a 'Therapeutic Assessment' (TA) versus 'Assessment as Usual' (AAU) when they initially presented to A&amp;E for self-harm.</p> <p>The application was been previously considered on the 4<sup>th</sup> October 2018 when IGARD had deferred making a recommendation pending; providing clarification on the current role of the co-investigator; to confirm that section 251 support is ongoing; to provide further information on the current involvement of the other parties referred to in the supporting documents; to</p>



	<p>provide further background on the original trial including the legal basis and consent process; to update the data minimisation wording within section 3(b) to add after “other reasons” the words “as outlined in the section 251 support.”; to include the following when referring to the GDPR legal basis “The NHS Act 2006 section 43(5), which describes the functions of authorised NHS Foundation Trusts, states that ‘The authorisation must authorise and may require the NHS foundation trust— (a) to carry out research in connection with the provision of health care, (b) to make facilities and staff available for the purposes of education, training or research carried on by others’.”; to update section 4 with the standard wording “All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after</p> <p><b>Discussion:</b> IGARD noted that the application had been updated to reflect all of the comments previously made.</p> <p>IGARD noted that there was no evidence of renewal of Health Research Authority Confidentiality Advisory Group (HRA CAG) support. NHS Digital advised that HRA CAG's position was that support would continue regardless of whether the HRA CAG register had been updated; IGARD asked that a special condition be included in section 6 (Special Conditions) that the applicant will notify NHS Digital without delay if HRA CAG support is revoked or amended.</p> <p>IGARD noted that reference was made to section 43(5) NHS Act 2006 in relation to the legal basis for Foundation Trusts within section 1(a) (Abstract), however suggested this should be moved to sit under the “Public Task” heading in the abstract.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To include a special condition that the applicant will notify NHS Digital without delay if HRA CAG support is revoked or amended.</li> <li>2. To move reference to section 43(5) NHS Act 2006 in relation to the legal basis for Foundation Trusts wording within the abstract under “Public Task”.</li> </ol>
2.12	<p><u>University of Edinburgh: Restart or Stop Antithrombotics Randomised Trial (RESTART)</u> (Presenter: Dickie Langley) NIC-149576-G6M4B</p> <p><b>Application:</b> This was a new application for identifiable Hospital Episode Statistics (HES) and Civil Registrations data for a study looking at the potentially beneficial effects of starting antiplatelet drugs (one or more of aspirin, clopidogrel or dipyridamole, chosen by the patients physician), on the risks of a heart attack, stroke and other clotting problems as well as their effect on the risk of a brain haemorrhage happening again, for adults surviving a stroke due to bleeding in the brain and who were taking a prescribed antithrombotic (i.e. anticoagulant or antiplatelet) drug for the prevention of illnesses such as angina, heart attack or stroke before their bleed.</p> <p><b>Discussion:</b> IGARD noted the information in supporting document 4.2, the British Heart Foundation funding letter that states that funding for salaries is only secured until the end of February 2019 and asked that section 1(a) (Abstract) is amended to clarify that NHS Digital have satisfied themselves that the employees of the University of Edinburgh working with the data and the study will continue their work beyond February 2019.</p>

	<p>IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5(b) (Processing Activities) of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement.</p> <p>IGARD noted that the trial database created will not contain any NHS Digital data and asked that this be added as a special condition in section 6 (Special Conditions).</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend the abstract to clarify that NHS Digital have satisfied themselves that the employees of the University of Edinburgh working with the data and the study will continue their work beyond February 2019.</li> <li>2. 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.</li> <li>3. To add a special condition confirming that the trial database created will not contain any NHS Digital data.</li> </ol>
2.13	<p><u>University of Birmingham: MR321: Cohort study of mortality and cancer incidence in UK oil refinery and petroleum distribution workers (1951-2016) (Presenter: Dickie Langley) NIC-324388-L6C2Q</u></p> <p><b>Application:</b> This was a renewal application for pseudonymised Medical Research Information Service (MRIS) for use in the cohort mortality study of UK oil refinery and petroleum distribution workers, which will help the UK Health and Safety Executive (HSE) and the EU Scientific Committee for Occupational Exposure Limits (SCOEL) in assessing whether current national and EU regulations provide adequate protection to workers exposed to particularly in relation to risks of acute myeloid leukaemia and myelodysplastic syndrome.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance and value of the long running study.</p> <p>IGARD queried if any consideration had been given by the applicant to engage surviving cohort members and also how they are communicating the outputs / benefits / results to those individuals still in the industry.</p> <p>IGARD noted the Energy Institute's technical project specification that was provided in supporting document 4 and queried how, in accordance with this, the funder is involved with the project and asked that they provide confirmation of this, and that they will not have influence on the outcomes nor suppress any of the findings of the research.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To give further consideration how the applicant is engaging with cohort members who are still surviving and how they are communicating the outputs / benefits / results to those individuals still in the industry.</li> <li>2. In accordance with the Energy Institute's technical project specification (Supporting document 4), to confirm how the funder is involved with the project and provide confirmation that they will not have influence on the outcomes nor suppress any of the findings of the research.</li> </ol>
2.14	<p><u>University Hospitals Birmingham NHS Foundation Trust: UHB SHMI Data Application (Presenter: Dickie Langley) NIC-381984-B7X3S</u></p> <p><b>Application:</b> This was a renewal application for pseudonymised Summary Hospital-level Mortality Indicator, Civil Registrations data and Hospital Episode Statistics (HES) data. Quarterly</p>

	<p>Summary Hospital Mortality Indicator (SHMI) data will be used to look at outcomes analysis and form analytical overviews relating to post discharge mortality. Such overviews relate to standardised post discharge mortality monitoring within distinct clinical cohorts and bespoke long-term survival monitoring. This work will increase the understanding of complete pathways of care since SHMI data shows which patients died following discharge from hospital. The objective is to provide quality care benchmarking analysis that will enable NHS organisations to deliver better services for patients.</p> <p><b>Discussion:</b> IGARD queried if the East Midlands Academic Health Sciences Network still had access to the data and asked for clarification that they will no longer be entitled to do so.</p> <p>IGARD queried if where an individual has access to patient-level data it is only permitted for patients treated at the user's organisation and asked that this be included as a special condition in section 6 (Special Conditions).</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To clarify that the East Midlands Academic Health Sciences Network who previously had access to the data will no longer be entitled to do so.</li> <li>2. To include as a special condition <i>"Where an individual has access to patient-level data it is only permitted for patients treated at the user's organisation."</i></li> </ol>
3	<p><b>AOB</b></p> <p><b><u>NIC-184951-D1G8R - Intensive Care National Audit &amp; Research Centre</u></b></p> <p>IGARD noted that following the 29<sup>th</sup> November 2018 meeting, when IGARD had deferred making a recommendation. The relevant extract is as follows:</p> <p>"IGARD deferred making a recommendation, pending:</p> <ol style="list-style-type: none"> <li>1. The applicant to clarify the responsibilities and powers of the Chief Investigator (as an employee of the University of Oxford) and what discretion they have in the overall project and therefore consider whether University of Oxford be considered a joint Data Controller.</li> <li>2. To update the abstract to list the GDPR legal basis for the Renal Association to flow the data to NHS Digital."</li> </ol> <p>NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee.</p>

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 14/12/18

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)
None						

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

- None notified to IGARD