Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 1 November 2018

Members: Joanne Bailey (items 2.1-2.6 and 2.12), Anomika Bedi (Acting Chair), Nicola Fear, Eve Sariyiannidou.

In attendance: Dave Cronin, Louise Dunn, Rachel Farrand, James Humphries-Hart, Dickie Langley, Vicki Williams.

Observer: Stuart Blake

Apologies: Sarah Baalham, Kirsty Irvine

1	**Declaration of interests:** Nicola Fear noted a professional link with the team at Kings College London [NIC-147957-4444C University of Oxford] and would not be part of the discussion. It was agreed Nicola would not remain in the meeting for the discussion of that application. Nicola Fear noted a professional link to Kings College London [NIC-150435 University Hospitals Birmingham NHS FT], but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The outcomes of the 18 October 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting. The minutes of the 18 October 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	Imperial College London: the power of connections – mapping behaviour of health care networks (Presenter Louise Dunn) NIC-67398-K2Y3T **Application:** This was a renewal to continue with additional Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Outpatient and HES Critical Care (CC) and an amendment to add an additional purposes to the agreement for processing the data for the applicant to create two additional databases. The data is required to analysis how patients move through the health care system with a view to improve the 'supply and demand' between hospitals and within networks to improve patient outcomes and experiences and to make efficiency savings. **Discussion:** IGARD noted that the abstract referred to a special condition in section 4, fair processing, and suggested that it be removed, since it was not relevant under this application. IGARD noted reference to a named supervisor within the abstract and suggested this be removed or updated to include the correctly named supervisor. IGARD noted that section 5a should be updated to include clearer examples for processing and how the applicant has been using the data. IGARD also suggested that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including a clear plan and specific examples of public / patient engagement.

	It was noted that five databases were outlined within the application and it was suggested the narrative be updated to be clear how the data held by the applicant and data requested under this application will be utilised by the three old databases and two new databases. IGARD also suggested that the application be updated to confirm that the data provided would be used for both the existing purposes as well as the new purposes outlined in section 5 of the application. IGARD queried the maternity data being requested and suggested that section 5 be updated to clearly describe how the use of maternity data in the research being undertaken aligned with the remit of the Department of Surgery and Cancer. IGARD also asked for clarity on the statement *"it is expected that this work will be completed within three months of receipt of the data*" and to confirm if the new data requested would be used for the PhD thesis. **Outcome:** recommendation to approve subject to the following conditions: 1 To provide further details of pathways of dissemination of the outputs including any specific examples and also provide a clear plan of public / patient engagement 2 To clarify within section 5 why maternity data is required, and bearing in mind that the data is to be used by the Department of Surgery and Cancer, to clearly describe how the use of maternity data in the research being undertaken aligns with the remit of the Department of Surgery and Cancer. The following amendments were requested: 1 The narrative with regard to the 5 databases (3 old and 2 new) outlined in the application to be updated to make it clear how the data already held by the applicant and the data requested under this application will be utilised by each of the 5 databases. Furthermore to update the application to confirm that the data provided will be used for both the existing purposes as well as the new purpose outlined in section 5. 2 To clarify references to "it is expected that this work will be completed within three months of receipt of the data" as outlined within the application, and confirm if the new data requested is to be used for the PhD thesis. 3 To remove reference to the fair processing notice special condition, since it is not relevant under this application. 4 To remove reference to the named supervisor within the abstract. It was agreed the condition be approved OOC by IGARD members
2.2	<u>Imperial College London: bespoke extract – HES / Civil Registration Mortality Extract (Presenter: Louise Dunn) NIC-383203-Q8B9L</u> **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data and Civil Registrations data to measure the quality of healthcare delivery by healthcare providers, this work also includes comparing hospital mortality rates, calculate total post-operative mortality rates and assess potential quality of care issues by comparing the cause of death with the reason(s) for admission. The application had been previously considered on the 11 October when IGARD had deferred making a recommendation pending: further explanation be given within Section 5 of how the datasets will be kept separate, in particular that the mortality data will not be linked to identifiable data, and to include a further description of security measures in place; amend section 5 and the abstract to clarify the process undertaken by NHS Digital in assessing and confirming that the data is not identifying and to make consequential amendments throughout the document, where necessary, to reference data as being either "identifying" or identifiable; 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 the correct

	subsection reference under the DPA 2018; include a brief statement at start of sections 5(c) and 5(d) outlining the intentions for the future of the project and if they are the same outputs / benefits as existing projects and to clearly state that the projects and work previously described are ongoing. **Discussion:** IGARD noted that application had been updated to address most of the comments previously raised. IGARD noted that the Imperial College London Dr Foster Unit was described as the Data Controller and that processing was taking place at Dorset Rise where the Imperial College London Dr Foster unit and staff were based and asked for confirmation of the identity of the organisation that is a party to the Data Sharing Framework Contract (DSFC) and that none of the NHS Digital data was stored on equipment or facilities provided by Dr Foster Limited. NHS Digital confirmed that Imperial College London was the Data Controller and that they would also be processing data received by NHS Digital and further confirm that Imperial College London were the contracting entity to the DSFC under which this Data Sharing Agreement (DSA) would sit. NHS Digital also noted that the staff accessing the data under this application were substantive employees of Imperial College London and that all data was being stored on and processed on Imperial College London equipment at their facilities. IGARD queried who would have access to the data and asked that section 5(b) be updated to explicitly state that no record level data will be accessed by third parties. It was also suggested that the application be updated to confirm that there would be no attempt to re-identify data by the applicant or any third party. IGARD queried what the intention was for the future of the project and asked for a brief statement at the start of sections 5(c) outlining this and to clarify if the future projects outputs / benefits are the same outputs / benefits as for existing projects and if so to clearly state that the projects and work previously described are ongoing. IGARD queried the process undertaken by NHS Digital in assessing and confirming that the data was not identifying and suggested that section 5 and the abstract be updated to make amendments throughout to correctly reference the data as being 'identifying' not 'identifiable'. IGARD also queried whether the linked HES mortality data would be identifiable or not and whether patient objections applied. It was suggested that a consistent approach be taken between patient objections previously applied and the application of patient objections with regard to current data disseminations and if any non-alignment in approach, that the appropriate justification be provided. It was suggested that the application be updated to correct any typos. **Outcome:** recommendation to approve subject to the following condition: 1 To amend section 5 and the abstract, to clarify the process undertaken by NHS Digital in assessing and confirming that the data is not identifying and to make consequential amendments throughout the document, where necessary, to reference data as being either "identifying" or "identifiable" and in addition to confirm whether linked HES mortality data will be identifiable or not and whether patient objections apply. As part of this, to confirm whether there is a consistency in approach taken between patient objections previously applied and the application of patient objections with regard to the current data dissemination. If any non-alignment in approach, then appropriate justification to be provided. The following amendments were requested: 1 To provide confirmation that no record level data will be shared with third parties unless fully justified within the application only those permitted under this application.

	2 Confirmation that there will be no attempt to re-identify data by the applicant or 3rd party. 3 To include a brief statement at start of section 5(c) outlining the intentions for the future of the project and if they are the same outputs / benefits as existing projects and to clearly state that the projects and work previously described are ongoing. It was agreed the condition be approved OOC by IGARD members
2.3	<u>Imperial College London: quarterly HES extract – health policy HES projects (Presenter: Louise Dunn) NIC-315716-L0F4M</u> **Application:** This was an amendment and extension request for a further 12 month agreement to retain data for project two, the quality of care for elderly patients with chronic conditions study, which had an amended purpose and to transfer the data under this agreement for both processing and storage to the Imperial College Big Data Analytical Unit. The aim of the research initially was to evaluate risk factors that lead to functional health decline in the elderly population with chronic conditions. Imperial College London indicated that they would like to amend this study to investigate the impact of government policies for improving quality and patient safety for frail patients. **Discussion:** IGARD queried if support from the funder continued to apply and NHS Digital confirmed that funding was still in place until the end of the agreement period. It was suggested that since the supporting documents provided referred to expired funding that it be clearly stated in section 5 of the application that projects 1, 3 and 4 had now been completed and this application was for project 2 and to additionally confirm that funding was still in place for the continuation of project 2 and provide relevant evidence such as a funding letter. IGARD queried the lack of measurable and yielded benefits for projects 1, 3 and 4 within section 5 along with examples of patient and public engagement in order to be transparent for the general public when this was published within NHS Digital's data release register and suggested further examples be provided for those completed projects. IGARD noted the project 2 used a subset of the whole dataset and queried why the applicant required to continue to hold the full dataset. NHS Digital noted that the applicant still required access to the data for projects 1, 3 and 4 in order to answer queries. It was suggested that the section 5 be updated to clarify that access to the data for the three completed projects was restricted so that data could only be accessed for the purpose of answering queries and that appropriate controls were in place to achieve this. IGARD suggested that it be explicitly stated within section 5 that applicable controls were in place to ensure that the data will only be accessed by the researchers for project 2 and that their access to data would be restricted so that they can only access the subset of data that would be necessary for project 2. **Outcome:** recommendation to approve subject to the following conditions: 1 To clearly explain within section 5 that projects 1, 3 and 4 have now completed and that this application is for project 2, and additionally to confirm funding is in place for the continuation of project 2 and provide relevant evidence. 2 To explicitly state within section 5 the applicable controls to ensure that data will only be accessed by the researchers for project 2 and to clarify that their access to data will be restricted so they only access that subset of data that is necessary for project 2. Furthermore to update the application to clarify that access to data for the three completed projects is restricted so that this data can only be accessed for the purpose of answering queries and that there are appropriate controls in place to achieve this. 3 To provide further examples of measurable and yielded benefits within section 5 of the

	application for the completed projects 1, 3 and 4. It was agreed the condition be approved OOC by IGARD members
2.4	<u>Royal National Orthopaedic Hospital NHS Trust: getting it right first time programme (Presenter: Rachel Farrand) NIC-14440-Q2G4W</u> **Application:** This was a renewal, amendment and extension application for pseudonymised Hospital Extract Statistics (HES) data to address incorrectly selected filters for the 2017/18 data and extend / renew the data sharing agreement (DSA). The Getting It Right First Time (GIRFT) programme aims to support improvements in clinical efficiency for 35 workstreams, 12 of which are surgical, 19 of which are medical and the remainder of which are cross-cutting. The HES data is used by the programme to calculate a range of activity and quality metrics for these specialities at hospital and clinical commissioning groups (CCG) summary level, which feed into the programme's outputs. **Discussion**: IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested and as per recent discussions between NHS Digital and IGARD, including listing the correct legal basis. It was also suggested that the application be updated to confirm that the Chair of Programme had overall responsibility for the processing of the data and that the sentence which starts "it ultimately reports to the Secretary of State for Health…" be removed since it is not relevant for this application. IGARD queried whether all organisations that had previously received data but were now no longer involved in the project had deleted any data held (and personnel had had their access revoked) and asked for further clarity on this. IGARD requested confirmation that data destruction certificate(s) had been issued with regard to any organisations which had previously held data but which were now no longer involved with the project. IGARD noted the involvement of University College London and asked for further clarification as to why they are not also considered as Data Controllers since they were an independent evaluator and applying for National Institute for Health Research (NIHR) funding. IGARD also queried the lack of outputs along with yielded benefits for University College London as part of this research, and suggested examples of patient and public engagement in order to be transparent for the general public when this was published within NHS Digital's data release register be provided. IGARD queried if funding was still in place and suggested that the application be updated to clearly state that funding was in place and provide evidence such as a funding letter. IGARD also queried who the GIRFT team were and how they were separate from University College London CLARC team and asked that confirmation be sought as to the makeup of each team. It was also queried as to who the other collaborating institutes were in the network and how they were involved, and suggested that section 5 be updated to be explicit on the identity of the other collaborating organisations in the network, how the other collaborating institutes within the network were involved and also confirming their role and any data they had access to. **Outcome:** recommendation to defer, pending: 1 To provide clarification in section 5 why UCL are not considered a Data Controller since they are an independent evaluator and applying for NIHR funding.

	2 To confirm within section 5 who the GIRFT team are and in what way they are separate to the UCL CLARC team, and additionally confirm which organisations form the makeup of each team. 3 Update section 5 to be explicit on the identity of the other collaborating organisations in the network as well as to explain how the other collaborating institutes within the network outlined in the application are involved, including their role and any data they may have access to. 4 To update the abstract with reference to Article 6 to reflect recent discussion between NHS Digital and IGARD to correctly list the appropriate legal basis. 5 To clarify within the abstract that the Chair of the Programme has overall responsibility for the processing of the data and remove the sentence which starts "it ultimately reports to the Secretary of State for Health…" since it is not relevant for this application. 6 The application should be amended to confirm that funding is in place and provide relevant evidence. 7 To provide further examples of measurable benefits and outputs for the work UCL have undertaken as part of this research. 8 To confirm that any organisation that had previously received NHS Digital data but now was no longer involved in processing it had confirmed to NHS Digital that they no longer held any NHS Digital data and that appropriate data destruction notices has been issued.
2.5	<u>3M United Kingdom PLC: data extract to support the continued accuracy of 3M developed quality and performance indicators for commissioners and providers (Presenter: Dickie Langley) NIC-91972-S9W9T</u> **Application:** This was an extension application to hold Hospital Episode Statistics (HES) Critical Care, Outpatient and Admitted Patient Care data for a further 12 months to anglicise a new 3M tool which provides software for clinical coding and analytical 'grouping' and an amendment to allow the applicant to update target dates within their purpose section. 3M solutions are used in approximately 80% of NHS Acute sector and this is typically in the form of clinical coding software such as Medicore Encoder or as part of the offering of a larger service provider. The application had been previously recommended for approval by IGARD on the 1st February 2018 for a period of seven months. **Discussion:** IGARD asked if NHS Digital had given consideration to Recital 162 of the General Data Protection Regulations (GDPR). NHS Digital noted that 3M UK Limited provided statistical products and services to clients and that the data would be processed by this private sector organisation . On this basis NHS Digital noted that Article 6(1)(f) (Legitimate Interests) and Article 9(2)(j) applied and furthermore that Recital 162 addresses processing for statistical purposes . Since processing is under Article 9(2)(j) of GDPR, the Data Protection Act (DPA) 2018 s10(2) requirement to meet a condition in DPA 2018 Part 1 of Schedule 1 is triggered. IGARD suggested that section 5 and the abstract be updated to explain the Legitimate Interests relied up and that NHS Digital assess the further justification on legitimate interests articulated by the applicant in the Legitimate Interest Assessment (LIA) they produced. Consideration should be sought as to how the LIA meets the requirements and the conditions of the legitimate interest legal basis. IGARD suggested that once NHS Digital are comfortable with the applicant's legitimate interest justification, reference should be made in the applications abstract that NHS Digital deemed it satisfactory. IGARD noted in section 5(b) that the applicant was using personal data to help develop their solution and noted an assumption that the data would remain in the UK, however they noted

	that there was also reference to cleansing the data and converting the codes to United States (US) equivalents. NHS Digital noted that 3M UK Limited were developing a clinical coding algorithm based on probability / aggregated data, however IGARD suggested that a special condition be included in section 6 and updated within section 5 that the applicant would use the data to develop a UK based tool for the benefit of the NHS and UK. IGARD noted variations of the name of the applicant and that the application should be updated to correctly reference the applicant, including clarifying whether 3M UK PLC and 3M were the same company and if they were not, to clarify their relationships and the involvement of each entity. IGARD suggested that confirmation be sought that the individuals accessing the data were substantive employees of applicant's UK based entity and that standard wording be included in section 5 with regard to access controls to access the data and that only members of the applicant's UK based entity would access the data, and that any access by employees of affiliates based outside of the UK would be in breach of this application / Data Sharing Agreement (DSA). IGARD noted that 98% of the applicant's client based was NHS clients, but asked for detail of the 2% client base which were not listed as being 'NHS clients'. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this DSA / applicant. **Outcome:** recommendation to defer, pending: 1 To include a narrative within the abstract and section 5 (purpose) explaining the Legitimate Interests relied upon and NHS Digital to further consider the justification on legitimate interests articulated by the applicant in the LIA produced by the applicant and how these meet the requirements and the conditions of the Legitimate Interest legal basis. Once NHS Digital is comfortable with the applicant's legitimate interests justification, reference should be made in the abstract that NHS Digital has deemed it satisfactory. 2 To clarify the name of the applicant, since a number of variations of the company name were used within the application, and to ensure consistency of naming throughout. 3 To clarify whether 3M UK PLC and 3M is the same company and if not to clarify the relationship and the involvement of each entity. 4 To confirm within section 5 that the individuals accessing the data are employees of the applicant's UK based entity and that any access by employees of affiliates based outside of the UK would be in breach of this DSA. 5 To provide details of the 2% client base which are listed as not being 'NHS clients' 6 To include a special condition in section 6 and update section 5 to reflect that the applicant is developing a UK based tool for the benefit of the NHS and UK. The following advice was given: 1 IGARD suggested that NHS Digital might wish to consider auditing this organisation in relation to this application / data sharing agreement. IGARD noted the importance of the work being undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, 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 address the queries raised by IGARD.
2.6	<u>Queen Mary University of London: a study to investigate the association between selective uptake of cervical cancer screening and all cause mortality (Presenter: Dickie Langley) NIC-</u>

15741-J6Y4L

Application: This was a new application for Civil Registration Mortality Data on a sample of deaths of women for use in the study 'a study to investigate the association between selective uptake of cervical cancer screening and all-cause mortality' which has been designed to understand whether women who suffer health problems or have riskier lifestyles are less likely to attend cervical screening, using a sample of women who died between 1992 and 2012 aged between 20 and 69 in 1992.

Discussion: IGARD noted this was an interesting study and welcomed the application.

IGARD noted that the application did not clearly identify the cohorts and suggested using consistent terminology throughout the applications stating that the cohort was limited to women ages between 20 and 69 in 1992 and between the time period 1992 and 2012. It was also suggested that the abstract, sections 3 and 5 be updated to clearly explain the cohort, including its size.

IGARD noted reference to phase 1 and phase 2 and suggested that the applicant provide further detail on these phases and explain how they will identify the cases and identify the control / comparison group within the abstract and section 5 of the application. It was also suggested that the term 'sub-cohort' be clear that this refers to a different category within the same cohort.

IGARD noted that it was not clear the legal basis relied upon for the data flows between NHAIS and NHS Digital and NHS Digital and NHIAS and suggested that further narrative be provided in the abstract explaining the lawful basis relied upon and clarify in section 5 why NHAIS were not considered as a joint Data Controller. It was also suggested that reference to "*The files shared between NHS Digital and NHAIS for identification of cohorts consists of personal identifiers and a PseudoID only. They DO NOT include mortality or screening data*." be deleted from within section 5.

IGARD suggested that the applicant provide further details of pathways for disseminating the expected benefits of the study to patients and the public including specific examples of public / patient engagement and a clear pathway for dissemination.

IGARD queried if funding was in place and suggested that the application be updated to clearly state that funding was still in place for the duration of the study outlined in the application and provide evidence such as a funding letter from Cancer Research UK.

It was suggested that evidence be provided as to how the applicant had dealt with the specifics of support detailed in the Health Research Authority (HRA) Confidentiality Advisory Group (CAG) support letter provided, dated 2016, with the application and in particular how the applicant will deal with patient notifications, noting that they would have had an annual review in 2017.

IGARD noted that references to '…cause of death specified above…' be updated within section 5(b) to clarify what this is and as outlined in the study protocol supporting document provided.

Outcome: recommendation to defer pending:

1. To use consistent terminology throughout the application that the cohort is limited to women aged between 20 and 69 in 1992 and between time period 1992 and 2012
2. To update the abstract, section 3 and section 5 to clearly explain the cohort including its size.
3. To provide further narrative in the abstract explaining the lawful basis relied upon for the data flows between NHAIS and NHS Digital and NHS Digital and NHAIS, as set out in the application, and clarify in section 5 why NHAIS are not considered a joint Data

	Controller 4. To provide further detail within the abstract and section 5 on the references to phases 1 and 2 outlined within section 5 and explain how the applicant will identify the cases and identify the control / comparison group 5. To provide more detail of the expected benefits within section 5 of the application with a clear pathway of dissemination 6. To provide evidence of how the applicant has dealt with the specifics of support detailed in the HRA CAG support letter, and in particular how they will deal with patient notifications. 7. The application should be updated to confirm that funding is in place and provide relevant evidence from Cancer Research UK 8. To delete the reference to 'The files shared between NHS Digital and NHAIS for identification of cohorts consists of personal identifiers and a PseudoID only. They DO NOT include mortality or screening data." from within section 5,. 9. To amend the term 'sub-cohort' to be clear this refers to a different category within the same cohort. 10. To update section 5 when referencing '..cause of death specified above…' to clarify what this is, as outlined in the protocol.
2.7	<u>University Hospitals Birmingham NHS FT: Linking and Evaluation of SABR CTE Patients (Presenter: Dickie Langley) NIC-150435-R7X1Q</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) data for the Stereotactic Ablative Radiotherapy (SABR) Study. SABR is a specialised radiotherapy treatment planning technique resulting in a high dose to the target with steep dose gradients resulting in rapid dose fall off outside the target area. This results in high biologically effective dose (BED) while minimising the dose received by the normal tissues and could potentially minimise the radiotherapy treatment toxicity and side effects. The application had been previously considered on the 18th October 2018 when IGARD had deferred making a recommendation pending: providing further information on the role of KiTEC and to confirm their legal status, including details of their "collaboration" with Guy's and St Thomas' Medical Physics Department; update the data flow diagram to contain a brief reference to the legal basis for each data flow and which is consistent with the data flows set out in the application provided; change references from 'non-identifiable' data to 'pseudonymised' data within section 5; provide a list of all data linkages within section 5(b) immediately before the statement that there will be no linkages other than as permitted in this agreement; update references within section 5(b) 'the database' to clearly state this is referencing the 'commissioning through evaluation database'; provide further detail on the patient and public outcome facing outputs; update the reference in the application to consent being taken, to the past tense. **Discussion:** IGARD noted the application had been updated to address most of the comments previously raised. IGARD noted that reference in the application to consent being taken was noted in the present tense and asked that this be updated to the past tense. IGARD noted that the data flow diagram provided had been updated to contain a brief reference to the legal basis for each data flow consistent with the data flows set out in the application provided, however suggested that the data flows between NHS Digital, KiTEC and UHB and between UHB and NHS Digital be clearly explained within section 5(b) of the application to reflect the updated data flow diagram. It was also suggested that data linkages undertaken be clearly explained in section 5(b) of the application and that the applicant will not

	link data in this application except those permitted under this application / Data Sharing Agreement. NHS Digital noted that UHB had created a database on the instruction of Kings College London and that they were managing and administering it on their behalf and that Kings College London remained the sole Data Controller. IGARD suggested that the abstract and sections 5(a) and 5(b) be updated to clear that in creating the database, UHB were acting upon the instruction of Kings College London and that UHB will be acting on the instruction of Kings College London to manage and administer the current database. It was also suggested that section 5 and the abstract be updated to clearly state that Kings College London are the sole Data Controller. In addition to this update, IGARD suggested removing the sentence "*UHB intends to establish a research database where these (sic) data will be stored in the long term…*" from section 5(a) since it is not relevant to this application. **Outcome:** recommendation to approve subject to the following conditions: 1 To remove the sentence "UHB intends to establish a research database where these data will be stored in the long term…" from section 5(a) since it is not relevant to this application. 2 To clearly explain in detail the data flows between NHS Digital, KiTEC and UHB and between UHB and NHS Digital to reflect the updated data flow diagram, and clearly explain the data linkages which are undertaken within section 5(b). 3 To update the abstract and sections 5(a) and 5(b) to be clear that in creating the database, UHB acted on the instructions of Kings College London and that UHB will be acting on the instruction of Kings College London to manage and administer the current database and clearly state that Kings College London are the sole Data Controller. The following amendment was requested 1 To update the tense within the application to the past tense. It was agreed the condition be approved OOC by IGARD members
2.8	<u>NHS Arden and Greater East Midlands CSU – NHS England Comm (Presenter: James Humphries-Hart) NIC-212898-X4C9W</u> **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Diagnostic Imaging Data Set (DIDS) and National Cancer Waiting Times Monitoring Data Set (CWT) and Children and Young People's Health Service (CYPHS). This application relates to the commissioning responsibilities that NHS England is directly responsible for and will be processed by Regional Teams across England. The application had been previously considered on the 4th October when IGARD had deferred making a recommendation pending: clarify if the data controller has already received the data requested under this application for commissioning purposes, and if yes to clarify how the commissioning purposes under this application are different from the commissioning purposes outlined within other applications; clearly explain how invoice validation within the application is different from other forms of invoice validation undertaken by CCG's in general; clarify within section 5 and section 3(b) if any further data minimisation can be undertaken by the applicant; amend section 5(b) to remove the paragraph starting "Patient level data will not be shared outside of the CCG…" since it is not relevant to this application; remove various special conditions in section 6 which refer to the ICO Anonymisation Code of Practice, identifiable data and appropriate fees being paid by the 25th May 2018; include as a special condition the final paragraph of section 5(b) "Patient level data will not be shared outside of the data

	controller…"; include within section 5 the special condition outlined in section 6 "For clarity any access by Interxion, Ilkeston Community Hospital and Pulsant to data held under this agreement would be considered a breach of the agreement…"; update section 4 to clearly state the applicant's fair processing notice "does not" meet the NHS Digital's fair processing criteria for privacy notices. **Discussion:** IGARD noted that application had been updated to reflect all the comments previously raised. IGARD noted that bullet point 3 within the abstract which started "Direct commissioning activities are undertaken by 5 NHS Regional Teams…" should be included within section 5 of the application. IGARD queried if the applicant was receiving pseudonymised data only and NHS Digital confirmed they were and so it was suggested by IGARD that reference to identifiable data within section 6, special conditions, be removed since it was not relevant to this application. **Outcome:** recommendation to approve The following amendments were requested: 1. To include from the abstract bullet point 3 "Direct commissioning activities are undertaken by 5 NHS Regional Teams…" within section 5. 2. To remove reference to identifiable data from section 6, special conditions, since it is not relevant for this application.
2.9	<u>University College London: MR1482 Prognosis in Palliative Care Study II (PiPS2) (Presenter: Kimberley Watson) NIC-221454-Z7R2K</u> **Application:** This was a new application for a one off identifiable Medical Research Information Service (MRIS) list clean (patient identifiers linked to date of death, fact of death and exit / entry to NHS). The PiPS2 was developed in response to a commissioned call for research by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme with the overall purpose to validate models of survival to improve prognostication in advance cancer care to include the Prognosis in Palliative Care Study (PiPS) predictor models. **Discussion:** IGARD noted this was a NIHR funded application and suggested that NHS Digital satisfy itself that funding was still in place by reviewing any evidence provided by the applicant. IGARD queried who the Priment Clinical Trials Unit and End of Life Care Intelligence Network were and if they were part of University College London and suggested that this be clearly stated within section 5 of the application. IGARD noted that previous Research Ethics Committee (REC) approval had asked that the applicant's Patient Information Sheet, supporting document 2, be updated and suggested that NHS Digital be satisfied that it was updated as part of REC approval. **Outcome:** recommendation to approve The following amendments were requested: 1. To clearly state within section 5 who the End of Life Care Intelligence Network are and that the Priment Clinical Trials Unit are part of UCL. The following advice was given: 1 NHS Digital should satisfy itself that funding is in place by reviewing any evidence. 2 NHS Digital should satisfy itself that the applicant has updated their Patient Information

	Sheet as per REC approval.
2.10	University College London: Precision in Provision: Predicting Treatment Outcome and Resource Use in Child Mental Health (Presenter: Kimberley Watson) NIC-140981-R5W6Z **Application:** This was a new application for pseudonymised Mental Health Services Data Set (MHSDS) data extract for use in child and adolescent mental health in children and young people aged 2 to 25. There is a lack of evidence about which characteristics of a young person are associated with treatment outcome and resource use and this research aims to address this gap and thereby expand the use of data resources for mental health research whilst at the same time develop the skills base in data linkage. The application had been previously considered on the 30th August 2018 when IGARD had deferred making a recommendation pending: NHS Digital to refer to an explicit policy on the University College London website that clearly states that ethics approval is required when dealing with children and young people, and suggested NHS Digital clarify this with the applicant; explanation of the answer of "no" to the question in question set 2 of the HRA Ethics Tool; confirmation within section 5 of the application that the individuals accessing the data have the appropriate honorary contract in place which will include a clause that the substantive employer of the person under the honorary contract will take appropriate action in the event of a breach and that the honorary contract will need to be in place and a copy be provided; the application should be amended to confirm that funding is in place and provide relevant evidence; the data minimisation table in section 3(b) should be updated to clearly outline the filters applied to reflect the study outlined within the application; provide further clarity with regard to the secondary purpose including confirmation this is not a separate project and no other parties are involved, the linkages to be undertaken and the context and purpose of linkage; 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 least within 1 month"; the applicant should work with NHS Digital on a fair processing notice that is GDPR compliant including; providing a privacy notice outlining the project and removing misleading statements referencing anonymised data and informed consent being different to consent under GDPR. **Discussion:** IGARD noted that application had been updated to reflect most of the comments previously raised. IGARD noted that the applicant had provided confirmation that the University's ethics committee had provided ethics approval, however IGARD requested, that confirmation be sought that IRAS ethics approvals is not also required. IGARD noted that point 2 previously raised was still outstanding. **Outcome:** recommendation to approve subject to the following condition: 1. Confirmation be provided that NHS REC ethics approval is not also required **Action:** The IGARD Chair to raise the status of organisational ethics approvals with the Director Data Dissemination to explore a new standard and the setting of the data protection framework
2.11	Intensive Care National Audit & Research Centre (ICNARC): Renal Replacement Anticoagulant Management (RRAM) (Presenter: Kimberley Watson) NIC-184951-D1G8R **Application:** This was a new application for one off extracts of Hospital Episode Statistics (HES) Admitted Patient Care (APC) and Civil Registration (death) data sets for the Renal

	Replacement Anticoagulation Management (RRAM) study which has been designed to utilise routinely collected data to compare the clinical and cost effectiveness of changing to citrate anticoagulation for continuous renal replacement therapy (CRRT) in adult intensive care units (ICO). The application had been previously considered on the 13th September 2018 when IGARD had deferred making a recommendation pending: update the application to reflect that the UK Renal Registry is a joint Data Controller; provide the legal basis under GDPR for the flow of data from the UK Renal Registry to NHS Digital; confirm within the abstract and section 5 if 'gender' will be used for the linkage purposes, since the CAG support letter clearly states that 'gender' is for analysis only; clarify the involvement of University of Oxford, Oxford University NHS Foundation Trust and John Radcliffe Hospital Oxford as outlined in the supporting documents provided, including their role and responsibilities and any access to data; clearly describe the three data linkages being undertaken within section 5; include narrative within the abstract and the purpose section of the application explaining the Legitimate Interests relied on and to make reference in the abstract that NHS Digital has considered the LIA produced by the applicant; update the data flow diagram provided to clearly reference the data flows and three data linkages outlined in the application, for example by including an additional legend; update reference to 'patient identifiers' to 'direct patient identifiers'. **Discussion:** IGARD noted that application had been updated to reflect most of the comments previously raised. NHS Digital noted that ICNARC had responsibility for the day to day management and running of the study and that chief investigator, based at University of Oxford, was not part of the research team nor accessing the data provided by NHS Digital. However, IGARD noted that Chief Investigator did have overall responsibility for the study and queried whether his employer should be listed as a Data Controller and suggested that ICNARC clarify its role and that of the Chief Investigator and University of Oxford. IGARD queried what discretion each has in the overall project and suggested consideration should be given as to whether the University of Oxford should be considered as joint Data Controller. IGARD suggested that the applicant may wish to utilise the Information Commissioner's Office (ICO) guidance with regard to identifying Data Controllers. IGARD noted that the Renal Association were part of the process and queried whether they should be considered as a joint Data Controller and asked that clarification be provided within section 5 as to why they are not considered a joint Data controller. IGARD suggested that the applicant may wish to utilise the Information Commissioner's Office (ICO) guidance with regard to identifying Data Controllers. **Outcome:** recommendation to defer, pending: 1. ICNARC to clarify its role and that of the Chief Investigator and the University of Oxford and what discretion each has in the overall project and therefore consider whether University of Oxford be considered a joint Data Controller, and that the applicant may wish to utilise the ICO guidance with regard to identifying Data Controllers. 2. To provide an explanation within section 5 why the Renal Association are not considered a joint Data Controller and that the applicant may wish to utilise the ICO guidance with regard to identifying Data Controllers.
2.12	University of Oxford: MR1134 the Oxford Monitoring System for Attempted Suicide – mortality following deliberate self-harm (Presenter: Dickie Langley) NIC-147957-4444C **Application:** this was a renewal and extension of a previously Data Sharing Agreement (DSA) to permit the retention and reuse of Personal Demographics data and mortality data that had

	been provided via NHS Digital's Medical Research Information Service (MRIS). This was one of three linked Data Sharing Agreements (NIC-147916-DPQ3Q and NIC-147907-MLK7R) whereby three organisations were involved in the multi-centre study of self-harm permitting them to share identifiable data with NHS Digital and pseudonymised data with each other. The Oxford Monitoring System for Attempted Suicide involves data collection on all presentations to the general hospital in Oxford following deliberate self-harm (also termed attempted suicide) and was established in 1976 to investigate the epidemiology, risk factors, clinical management and outcomes in patients who present to hospital following self-harm. **Discussion:** IGARD noted the interlinked nature of this application to NIC-147916-DPQ3Q and NIC-147907-MLK7R, in particular the Data Controllership arrangements. IGARD queried the Data Controllership and the information provided in step 2 the data flow diagram. After some discussion, it was noted that it should also be explicitly stated in section 5 of the application that the data flowed from the University of Oxford to the University of Manchester and that where University of Oxford merges the data with the two other extracts, that the University of Oxford are the Data Controller at that stage of the process . IGARD noted that the application referred to the whole project as a 'study' however it was suggested that application be updated to clearly state whether stage 1 was for audit or study research. IGARD noted that it was unclear if funding extended beyond March 2019 and suggested that the application be updated to clearly state that funding was still in place for the duration of the project outlined in the application and provide relevant evidence such as a funding letter from the Department of Health. IGARD noted that there was insufficient information of the history of the application and asked that the abstract be updated to accurately reflect this and how this application interlinks with NIC-147916-DPQ3Q and NIC-147907-MLK7R IGARD noted that the abstract should be updated to ensure that Article 6 and 9 of the GDPR reflects recent discussions between NHS Digital and IGARD regarding the University of Oxford's legal basis. IGARD noted that the application stated that ethics approval was required via supporting document 4.5, and asked that evidence be provided of ongoing ethics support. NHS Digital noted Health Research Authority (HRA) Confidentiality Advisory Group (CAG) previous advice via s251 approval, supporting document 2.3, with regard the patient leaflet and IGARD agreed with the point raised and suggested that the applicant may wish to consider HRA CAG's advice via their annual review letter to "improve patient leaflet to include more details about the register…" In addition, when considering the matter from the viewpoint of transparency, it was IGARD's opinion that the patient notification arrangements were inadequate with regard to informing patients on the processing of their data and that the applicant may wish to seek advice from NHS Digital. IGARD noted that the comments raised were also applicable, where appropriate to the interlinked applications: NIC-147916-DPQ3Q and NIC-147907-MLK7R and suggested that all three applications come to the same meeting of IGARD for consideration. **Outcome:** recommendation to defer, pending: 1 To explicitly state in section 5 that where the data flows from the University of Oxford to the University of Manchester as set out in step 2 of the data flow diagram and where University of Oxford merges the data with the two other extracts, that the University of Oxford are the Data Controller at that stage of the process.

	2 The application should be amended to confirm that current funding is in place and provide relevant evidence. 3 To provide evidence of ongoing ethics support. 4 To update the abstract to give a clear history of the application to date and clear narrative of the three interrelated applications (NIC-147957-4444C, NIC-147916-DPQ3Q and NIC-147907-MLK7R). 5 To update the abstract on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD regarding the University of Oxford legal basis. 6 To clarify whether stage 1 is for audit or study research. The following advice was given: 1 IGARD suggested that all three interrelated applications come to the same meeting of IGARD for consideration (NIC-147957-4444C, NIC-147916-DPQ3Q and NIC-147907-MLK7R) 2 In considering the issue of transparency, it was IGARD's opinion that the Patient notification arrangements were inadequate with regard to informing patients on the processing of their data and that the applicant may wish to seek advice from NHS Digital. 3 IGARD suggested the applicant may wish to consider HRA CAG's previous advice via the Section 251 Approval – Annual Review letter to "improve patient leaflet to include more details about the register…"
2.13	<u>Cardiff University: MR826 – AML15 – MRC working parties on leukaemia in adults and children acute myeloid leukaemia trial 15 (Presenter: Dave Cronin) NIC-184980-J5B6C</u> **Application:** This was an extension and renewal application for Personal Demographics Service (PDS) and Civil Registration Mortality (date and cause of death) data for a long running medical research study which behand as a clinical trial and has since transitioned to a follow up study, with no longer any active participation by participants nor intervention with participants healthcare as a results of the trial / study. **Discussion**: IGARD noted NHS Digital's proposal to liaise with the Health Research Authority (HRA) Confidentiality Advisory Group (CAG) and agreed that the applicant obtain s251 support. IGARD noted that it was unclear within the application who within the cohort fell into which age bracket: 15 and under or 16 and over at time of consent. IGARD suggested that NHS Digital may wish to explore with the applicant splitting the application into two cohorts: 16 and over and 15 and under. The reason being that the existing consent may be sufficient for those individuals that were aged 16 and over who had consented under the consent materials provided with this application, however the applicant would need to be clear if those aged 16 to 18 had been treated as adults or minors when they had consented. IGARD noted concerns about the application including whether the duty of confidentiality with regard to minors had been addressed and whether all needed approvals and permissions had been obtained such as ethics approval. IGARD noted that the University of Birmingham had been removed as a Data Controller and queried if any copies of data held had been securely destroyed. NHS Digital confirmed they were not holding any data under this application and that section 5 would be updated to confirm. **Outcome:** unable to recommend for approval

	IGARD were unable to recommend for approval due to concerns about the quality of the application, including whether the duty of confidentiality with regard to minors had been addressed and whether all needed approvals and permissions had been obtained such as ethics approvals. IGARD agreed with NHS Digital's proposal to liaise with HRA CAG about the need for the applicant, to obtain s251 support. IGARD suggested that NHS Digital and the applicant may wish to consider splitting the application into two cohorts: 16 and over and 15 and under since consent may be in place for those adults, aged 16 and over, who had consented under the consent materials provided 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 had expired, 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 applications.
2.14	<u>University of Oxford: MR1113 – Study of Heart and Renal Protection (SHARP) post-trial (Presenter: Dave Cronin) NIC-147782-0D7TX</u> **Application:** This was a renewal application for Hospital Episode Statistics (HES) Admitted Patient Care (APC) from 2002/03 to latest available and a one off Members and Posting and Cause of Death report backdated to 2009 for cohort maintenance and reconciliation, funded by the UK Medical Research Council and sponsored by the University of Oxford. The SHARP trial was carried out in 18 countries with 1987 people in the UK being randomised and it assessed the effect of lowering LDL cholesterol with a combination of simvastatin 20mg plus ezetimibe 10mg versus a matching placebo on serious vascular disease (i.e. heart attacks, strokes) and renal disease (i.e. starting dialysis) events, with participants followed up regularly in study clinics, with all serious adverse events recorded. The SHARP trial finished in 2010 and concluded that around a quarter of all heart attacks, strokes and operations to open blocked arteries could by avoided in people with CKD by using a combination tablet to lower blood cholesterol levels. The aim of the SHARP post-trial follow up project is to carry out extended follow up of SHARP participants to determine the longer term effects. NHS Digital noted that section 5(b) would be updated with wording used in the abstract and section 6 to clearly describe that "*all duplicate data post-trial held from 2009 to 2017 will be destroyed in a secure manner, and NHS Digital provided with documentation of such destruction*". **Discussion:** 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. IGARD noted that it was not clear about the arrangements in place for the collection of data from the Renal Registry and that clarification be sought to specify who will collect the data and in this context to further clarify 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…*". It was suggested that NHS Digital satisfy itself that funding was still in place by reviewing any evidence provided by the applicant, from the UK Medical Research Council. IGARD noted that section 5(a) should be updated to include clearer examples of measurable benefits and how the applicant has been using the data. IGARD also suggested that the applicant provide further details of pathways for disseminating the measurable benefits of the

	trial to patients and the public including specific examples of public / patient engagement. IGARD noted the 2015 original s251 support provided, however it was not clear from the evidence provided whether the original 2015 s251 support (including any amendments subsequently made to the approval) was still in place. **Outcome:** recommendation to approve subject to the following conditions 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…". The following amendments were requested: 1 To update section 5(b) with wording used in the abstract and section 6 to clearly describe that "all duplicate data post-trial held from 2009 to 2017 will be destroyed in a secure manner, and NHS Digital provided with documentation of such destruction". The following advice was given: 1 IGARD suggested on renewal that further details of pathways of dissemination of measurable benefits be provided including examples of public / patient engagement. 2 NHS Digital to satisfy itself that funding is in place and the application should be amended to confirm that funding is in place. IGARD advised that they would wish to review this application again when it comes up for renewal. It was agreed the conditions be approved OOC by IGARD Members.
3 **3.1**	**AOB** <u>Multi-Party / joint controller applications to IGARD</u> IGARD noted their outstanding action from 15 March 2018 which had requested a briefing note be provided by NHS Digital clarifying the contractual arrangements in place, the structure, enforcement strategy and how the agreements worked together so that the data disseminated by NHS Digital would be protected. The Director Data Dissemination provided a update, via email after seeking advice from NHS Digital's Legal Team, noting that NHS Digital wishes to ensure that NHS Digital has the contractual framework appropriate for these type of applications (i.e. to protect the personal data disseminated), to allocate and manage the risks involved and to ensure that NHS Digital has in place the appropriate organisational and individual controls and mechanisms. The Director Data Dissemination requested that IGARD should assume when considering 'multi-party' applications, that this part of contract structuring will be appropriately handled, and as such proposed that this topic should not be a consideration factor each time that IGARD members reach an appropriate recommendation/outcome with regard to an application. The request was made for this approach to apply to all multi-party applications and therefore this topic will not be referenced in the minutes and outcomes relating to individual applications involving multi-party applicants. The Director Data Dissemination noted continued work on this topic and that a further update would be provided to IGARD in due course.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 26/10/18

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-144568-D7G6V -	Royal Brompton and Harefield NHS Trust	30/08/2018	To provide a clearer rationale for the inclusion of all myocardial infarction and cardiac arrest events or to minimise the data requested for those events, for example, filtered by age.	OOC by quorum of IGARD Members	Quorum of IGARD Members	N/A
NIC-03422-Y7Y0Z	University College London	11/10/2018	1. The application be updated to reflect the background and nature of the "Cancer Research UK and University College London Cancer Trials Centre" and to state that the funder Cancer Research UK (the charity) are not involved in the study, other than providing funding, nor will they have any influence on the results nor suppress any results.	OOC by quorum of IGARD Members	Quorum of IGARD Members	N/A
NIC-172240-R4R0L	University of Oxford	04/10/2018	1. To explicitly state that whilst there is a US cohort detailed within the application, no Harvard University employees will have no access to record level data.	OOC by quorum of IGARD Members	Quorum of IGARD Members	N/a

			2. Giving a clear explanation within section 5 of the application the roles and responsibilities of the TIMI Group in Harvard and The Medicines Company and to explicitly state that, notwithstanding anything to the contrary in the consent material, The Medicines Company will not access data under this agreement. 3. To insert a special condition in section 6 that the data will only be stored and processed in England / Wales. 4. To insert a special condition in section 6 that only employees from the University of Oxford can access the data. 5. To insert a special condition in section 6 that The Medicines Company will not influence nor supress results of the study. 1.			
NIC-204228-D8J4D	The Nuffield Trust	06/09/2018	1. To clarify the criteria for assessment and the scope of the proposed projects and to set out a framework criteria for those projects and how they will all fall within the same scope. 2. A clear explanation of how the data can be used within the	OOC by quorum of IGARD Members	Quorum of IGARD Members	N/A

			projects, what data is used and how it will be appropriately minimised in section 5(b). 1.			
NIC-50975-X6N3J	University College London	23./08/2018	1. The legal basis relied on for each flow of data should be justified to IGARD's satisfaction. This should be done by updating the application (and in particular supporting document 4 - the data flow diagram) to identify in detail the legal basis relied on for each flow of data. 2. To provide evidence of the renewal of the CAG approval. 1.	OOC by quorum of IGARD Members	Quorum of IGARD Members	N/a

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

- None notified to IGARD