Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 4 October 2018

Members: Sarah Baalham, Joanne Bailey (items 2.1–2.7, 2.9), Anomika Bedi (2.1-2.7, 2.9-2.10, 2.12-2.14), Kirsty Irvine (Chair), Eve Sariyiannidou.

In attendance: Dave Cronin, Chris Dew, Rachel Farrand, James Humphries-Hart, Peter Knighton, Dickie Langley, Victoria May, Karen Myers, Kimberley Watson, Vicki Williams.

Observer: Suzanne Shallcross.

Apologies: Nicola Fear.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 20 September 2018 IGARD meeting were reviewed and were agreed as an accurate record of the meeting. **Out of committee recommendations** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	<u>National Diabetes Audit (NDA) Core Data Briefing Paper (Presenter: Chris Dew, Peter Knighton, Victoria May)</u> **Briefing Paper:** The National Diabetes Audit (NDA) is part of the National Clinical Audit Programme. The NDA Core audit collects information about general diabetes care and measures the effectiveness of diabetes healthcare against NICE Clinical Guidelines and NICE Quality Standards, in England and Wales. There is also a number of other NDA Programme workstreams not included in the NDA Core which focus on specific diabetes care pathways. The purpose of the paper was to provide further information to IGARD. **Discussion:** IGARD thanked Chris, Peter and Victoria for attending the meeting, noted the contents of the briefing paper and offered the following comments: IGARD noted that it was not clear within the paper what has happened previously with the NDA and what is happening going forward and asked for a clearer statement outlining what was changing. IGARD queried if a Data Protection Impact Assessment (DPIA) had been completed. The presenters confirmed that it had been completed and IGARD asked for sight of this. IGARD noted that the Direction is for NHS Digital to be the data controller for the collection of data and queried the legal basis under the GDPR for the processing of data other than the data collection. IGARD asked that a copy of the technical specifications referred to in the Direction be shared with IGARD and recommended that it be explained clearly that the direction sets aside the common law duty of confidentiality. IGARD requested clarification of the role and involvement of HQIP as it has always acted as the Data Controller for the NDA and a further explanation suggesting that NHS Digital is the data controller for the audit data be included in the paper.

	IGARD noted the legal basis for the collection of data was a Direction and asked for evidence of the section 251 support for the Welsh data in the paper. IGARD asked for further clarification on the relationships and the actors involved in order to understand clearly the framework, structure and relationships. IGARD advised that the fair processing link in the document was not working and asked NHS Digital to check this. IGARD noted that section 6 of the paper is entitled "Compliance with the ICO Code of Practice". IGARD noted that it was unclear what code of practice the paper referred to and the bullet points in this section were not relevant to the ICO Anonymisation Code. NHS Digital noted that record level data would be available to researchers upon application and IGARD noted that these were clearly described in detail in the paper.
2.2	<u>Imperial College London: SAHSU annual renewal and amendment - HES (Presenter: Dickie Langley) NIC-204903-P1J7Q</u> **Application:** This was an amendment and renewal application for identifiable Hospital Episode Statistics (HES) and access to identifiable Civil Registration Data. The Small Area Health Statistics Unit (SAHSU) is a centre of excellence assessing the risk of exposure to environmental pollutants to the health of the population, with an emphasis on the use and interpretation of routine health statistics at small-area level and was established as a recommendation of the Black Enquiry into the incidence of leukaemia and lymphoma in children and young adults near the Windscale / Sellafield nuclear power plant. The application was been previously considered on the 20th September 2018 when IGARD had deferred making a recommendation pending; providing further clarity on the role of Public Health England, particularly in terms of the reference (in the abstract) to it having "full oversight" of the project and (in section 5(a) to being part of the approval process and liaison committee; 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"; to duplicate the clarification contained in the abstract about the "user under contract" within section 5; to provide the supporting documents referred to in the application. **Discussion:** IGARD noted that historic phrasing was being used in section 4 Fair Processing and it was suggested that the following standard wording be used: "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 of the data being disseminated." IGARD discussed the possible nature of the employment undertaken by the PhD students referred to in the application and suggested that NHS Digital satisfy itself as to the particulars of this. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 4 with the standard wording ""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 of the data being disseminated."

	2. To provide clarity that where there is a reference within the application to PhD students that it is clear that they are also employees of Imperial College London. The following advice was given: 1. In line with the CAG standard condition, NHS Digital should review, as appropriate, to ensure it cannot perform the linkage itself. 2. NHS Digital should ask for confirmation that the substantive contracts of employment for students are for purposes other than undertaking a PhD.
2.3	University Hospitals Birmingham NHS Foundation Trust: Linking and Evaluation of SABR CTE Patients (Presenter: Dickie Langley) NIC-150435-R7X1Q **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. **Discussion:**-IGARD welcomed the application and noted the importance of the study. IGARD noted that there were several phases to the project and asked for further clarity on the specific purpose of this application and the background, setting the scene that this application is for the analysis phase of the study only. IGARD queried the actors involved with the study and what the legal basis was for the flow of data and requested a data flow diagram clarifying this information. IGARD noted the involvement of the University Hospitals Birmingham (UHB) NHS Foundation Trust, the National Institute for Health and Care Excellence (NICE) and NHS England and asked for further clarification as to why they are not also considered as Data Controllers. IGARD queried the sentence in section 5(a) that states "'The patients will be consented separately to their treatment consent for their data to be analysed by KiTEC.' and for clarity asked that this be revised. IGARD noted that there were reference in the application to 'non-identifiable' data and asked that this be amended to correctly reference 'pseudonymised' data. IGARD advised that section 3(c) should be amended to state that patients' objections are not applied due to patient consent having been obtained. IGARD noted that section 5(b) states that the data shared from UHB and King's College London will "not be in identifiable form" and suggested removing this as it already states it is pseudonymised. IGARD queried whether there was any ongoing contact with the cohort outlined in the application and asked that clarification be included detailing this. IGARD suggested that the applicant provide further details on the patient and public- facing outputs. IGARD queried what the role of KiTEC was in the project as this was not clear and asked for further clarity on their legal status. IGARD suggested that updated standard wording in section 4 Fair Processing be used: "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 of the data being disseminated."

	IGARD noted that within section 5(b) it states the following "There will be no data linkage undertaken with NHS Digital data provided under this agreement that is not already noted in the agreement." and asked for a list of all data linkages to be grouped together within section 5(b), followed by this statement and for this list of linkages and statement to also be replicated within the special conditions in section 6 of the application. **Outcome:** Recommendation to defer, pending: 1. To clarify the purpose of the application particularly the circumstances leading to its creation and to confirm that this is for the analysis phase of the study only. 2. To provide a data flow diagram clearly noting the actors involved and the legal basis for the flow of data. 3. To provide clarification why University Hospitals Birmingham NHS Foundation Trust, The National Institute for Health and Care Excellence (NICE) and NHS England are not also considered Data Controllers. 4. For clarity, to revise the wording of the sentence 'The patients will be consented separately to their treatment consent for their data to be analysed by KiTEC.' 5. Change references from 'non-identifiable' data to 'pseudonymised' data. 6. To amend section 3(c) to note state that patient's objections are not applied due to patient consent. 7. To clarify data shared from University Hospitals Birmingham NHS Foundation Trust and King's College London will be pseudonymised (and remove the reference to it "not be in identifiable form"). 8. To provide details of any ongoing contact with the cohort. 9. To provide further details on the patient and public outcomes facing outputs. 10. To provide further information on the role of KiTEC in the project and to confirm their legal status. 11. To update section 4 with the standard wording ""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 of the data being disseminated." 12. To provide a list of all data linkages within section 5 immediately before the statement that there will be no linkages other than as permitted in this agreement and to replicate this list and statement within the special conditions.
2.4	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 **Application:** 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&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&E for self-harm. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted that supporting document 2 provided with the application referenced the co-investigator and queried what the current role was of the co-investigator and asked for further clarification of this. IGARD queried if the study's section 251 support was ongoing, since it was not clear, and asked for confirmation of this.

	IGARD noted that a number of parties are noted within the supporting documents as being involved with the study and asked for further information to be provided on this. IGARD asked for further details on the original trial and asked that further background information including the legal basis and consent process be clarified. IGARD noted the following statement within the table in section 3(b) "Data would be reduced to identifying whether the investigation and treatment provided was related to self-harm or other reasons." and advised that this should be amended to include "as outlined in the section 251 support" at the end of the sentence. IGARD suggested that when referring to the GDPR legal basis for Foundation Trusts in the application, the following should also be included "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'." IGARD noted that historic phrasing was being used in section 4 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 of the data being disseminated." IGARD suggested that the following statement within section 5(b) should also be included as a special condition in section 6 of the application: "All outputs will only contain results in highly aggregated format and as statistical summaries and measures of association. Small numbers will be suppressed in line with the HES Analysis Guide. Record level information will not be released to any third party." IGARD suggested that the applicant may wish to consider disseminating the outputs more widely the public, including adolescent mental health charities. **Outcome:** Recommendation to defer, pending: 1. Provide clarification on the current role of the co-investigator 2. To confirm that section 251 support is ongoing 3. To provide further information on the current involvement of the other parties referred to in the supporting documents. 4. To provide further background on the original trial including the legal basis and consent process 5. To update the data minimisation wording within section 3(b) to add after "other reasons" the words "as outlined in the section 251 support." 6. 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'." 7. 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 of the data being disseminated". 8. To duplicate the following from section 5(b) "All outputs will only contain results in highly aggregated format and as statistical summaries and measures of association. Small numbers will be suppressed in line with the HES Analysis Guide. Record level information will not be released to any third party." and include it as a special condition in section 6. The following advice was given: 1. The researchers may wish to consider disseminating outputs more widely to the public for example via adolescent mental health charities.
2.5	Health Innovation Network - South London: Health Innovation Network (south London AHSN) application for HDIS access (Presenter: Dickie Langley) IC-203509-L9P1P **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data. There are currently 15 Academic Health Science Network's (AHSN) in England, each works within its own region alongside Sustainability and Transformation Partnerships to respond to local health priorities. The 15 AHSNs also connect as a national Network to take what works locally and quickly spread it across large geographies. In July 2017 the NHS announced that the 15 AHSNs will be relicensed from April 2018 with an enhanced remit to operate as the innovation arm of the NHS. The AHSNs are currently working with NHS England, NHS Improvement, the Government's Office for Life Sciences and other partners, to develop the priorities for the new licence. These are likely to focus on themes including digital innovation, patient safety, quality improvement / system transformation and MedTech. **Discussion:** IGARD suggested that when referring to the GDPR legal basis for Foundation Trusts in the application, the following should also be included "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'." IGARD suggested that one of the special conditions noted in section 6 should also be replicated in section 5 of the application ""NHS Digital will monitor use of the NHS Digital on-line portal as part of on-going access and any excessive or unauthorised use will be reviewed and access could be withdrawn with data destruction notices issued if that occurs." and "Organisation is only permitted to download tabulated data with small numbers from the system. Downloading of record level data and record level linkage is not permitted under this agreement." IGARD queried who would have access to the data outlined in the application and asked that the application be updated to explicitly state that only Guy's and St Thomas' NHS Foundation Trust will have access to the data. IGARD queried which of the Domains outlined in the application the HES data would be used for and asked that it be made clear within the special conditions in section 6 that the HES data will only be used for Domain A, B and C not Domain D. IGARD queried the lack of outputs, a defined process within section 5 along with yielded benefits in order to be transparent for the general public when this was published within NHS Digital's data release register and suggested on renewal further information would be expected to be provided. **Outcome:** recommendation to approve

	The following amendments were requested: 1. 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'. 2. To replicate in section 5 the following special conditions in section 6 "NHS Digital will monitor use of the NHS Digital on-line portal as part of on-going access and any excessive or unauthorised use will be reviewed and access could be withdrawn with data destruction notices issued if that occurs." and "Organisation is only permitted to download tabulated data with small numbers from the system. Downloading of record level data and record level linkage is not permitted under this agreement." 3. To explicitly state within the application that only Guy's and St Thomas' NHS Foundation Trust will have access to the data. 4. To include a special condition in section 6 that the HES data will not be used for Domain D and only used for Domains A, B and C as outlined in the application. The following advice was given: 1. IGARD advised when the application returns to IGARD for renewal, IGARD would expect to see further information with regard to yielded benefits. The following observation was made: 1. IGARD noted that a briefing paper on the new online portal was forthcoming, it was IGARD's understanding that this application would be a continuation of the same level of access as previously received on the old system and that the outcome was not an endorsement of the new system.
2.6	<u>Royal College of Anaesthetists: MR1477 - EPIdemiology of Critical Care After Surgery (EPICCS) (Presenter: Kimberley Watson) NIC-88623-F2H1Q</u> **Application:** This was a new application for identifiable and pseudonymised Hospital Episode Statistics (HES) and identifiable Medical Research Information Service (MRIS) data. The study is a one-week observational study including all patients who underwent inpatient surgery between March 21st - 27th 2017. This study uses patient information to help improve care for people undergoing surgery. All patients had prospective data collection on risk factors, surgical procedure and postoperative outcomes including the primary outcome of morbidity and secondary outcomes including length of stay and inpatient mortality. The admission of high-risk patients to critical care after surgery is a recommended standard of care, however poor compliance against this recommendation has been repeatedly demonstrated in large epidemiological studies. **Discussion:** IGARD noted some confusion over the purpose of the study and the cohorts and asked for further details in section 5 with a more detailed description of the study / studies and asked that this be aligned with the information provided in the HRA CAG and the Protocol supporting documents. IGARD queried if the medical PhD that is referenced within supporting document 8 is the study or part of the study and asked for further clarification on this. IGARD noted the involvement of the University College London (UCL), University College London Hospitals NHS Foundation Trust (UCLH) and the National Institute for Health and Care Excellence (NICE) and the National Institute of Academic Anaesthesia's Health Services Research Centre (NIAA-HSRC) and asked for further clarification as to why they are not also

	considered as Data Controllers, as substantive employees of these organisations are listed in the Protocol as chief investigator and co-investigators. IGARD queried what the legal basis under common law extends to all cohorts and clinicians outlined in the application and the HRA CAG supporting documents, and asked for further clarification on this. It was noted that all Data Controllers outlined in the application would need to meet NHS Digital's fair processing criteria for privacy notices and suggested that the Data Controllers update their privacy notices to comply with GDPR, including being published and accessible. IGARD queried why HES APC data is required for the entire cohort of 23,000, since it was not clear within section 5 of the application, and asked for clear justification for this. IGARD noted that it was unclear in section 5 who would be accessing the data and what data they were accessing and asked for further clarification of this and asked that this this aligns with the HRA CAG approval. IGARD noted that the first reference of section 251 in the application does not reference the NHS Act 2006 and asked that this be amended. IGARD noted that the legal basis in section 3(b) refers to section 161(2)(b)(ii) which is incorrect and asked that this be amended to reflect the correct legal basis which is 261(7). **Outcome:** Unable to recommend for approval 1. Section 5 of the application should be updated to provide a more detailed description of the study or studies and the cohorts which aligns with the information provided in the HRA CAG and Protocol supporting documents . 2. Provide clarification if the medical PhD referenced in supporting document 8 is the entire study or part of the study. 3. To update the application to clarify why UCL, UCLH and NIAA-HSRC are not considered as joint data controllers. 4. To clarify what the legal basis under common law extends to all cohorts and clinicians under this application. 5. All data controllers to provide a fair processing notice and to ensure that it is compliant with the notice requirements under the GDPR. 6. To provide a clearer justification why HES APC data is required for the entire cohort. 7. To provide clarification in section 5 who is accessing the data and what data they are accessing and that this aligns with HRA CAG approval. 8. To include reference to the NHS Act 2006 when first referencing section 251 in the application. 9. To amend the legal basis in section 3(b) to refer to section 261(7) not section 261(2)(b)(ii).
2.7	<u>University of Oxford: MR1483 - HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease. Application for data for invitation. (Presenter: Dave Cronin) NIC-172240-R4R0L</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) and identifiable Medical Research Information Service (MRIS) data. The ORION-4 study will find out whether inclisiran safely reduces heart attacks, strokes and cardiovascular deaths in people who already have cardiovascular disease. If shown to be effective, this treatment could substantially reduce premature death and disability from these conditions. A secondary objective is developing streamlined trial methods that would benefit future research.

	Discussion: IGARD noted that the application details a US cohort and asked for the application to explicitly state that no Harvard University employees will have access to record level data. It was suggested that 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. IGARD noted that a special condition should be included in section 6 stating that the data will only be stored and processed in England and Wales. IGARD also advised that a special condition should be included in section 6 stating that only employees from the University of Oxford can access the data. It was also suggested a further special condition should be included in section 6 that The Medicines Company will not influence nor supress results of the study. IGARD asked for clarification as to whether the University of Oxford would be sharing the data and asked for section 5(a) to be amended to clearly state that the University of Oxford will not share data provided by NHS Digital with any other organisation apart from participating Trusts. IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 be updated to clearly state that the application privacy notice 'does not' meet the criteria. **Outcome**: recommendation to approve subject to the following conditions: 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. 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. The following amendments were requested: 1. To amend section 5(a) to clearly state that University of Oxford will not share data provided by NHS Digital with any other organisation apart from participating Trusts. 2. To 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. The following advice was given: 1. IGARD suggested that in light of, inter alia, the Clinical Trial Regulation requirements, the applicant may wish to update their consent materials to clearly state that withdrawing from the trial will not affect any future care. IGARD also noted that the applicant may wish to use the correct terminology of "withdrawal" rather than "opting out". It was agreed the conditions be approved OOC by IGARD Members
2.8	NHS Arden and Greater East Midlands Commissioning Support Unit: DSfC - NHS England - Comm (Presenter: James Humphries-Hart) NIC-212898-X4C9W

	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. **Discussion:** IGARD queried whether the data controller has already received the data requested under this application for commissioning purposes and if so to clarify how the commissioning purposes under this application differ from the commissioning purposes that are outlined within other applications. IGARD queried how invoice validation within this application is different from other forms of invoice validation undertaken by CCG's in general and asked for a further explanation on this. IGARD noted that the amount of data being requested in the application and asked for further clarity within sections 5 and 3(b) if any further data minimisation can be undertaken by the applicant. IGAD noted the following paragraph in section 5(b) "Patient level data will not be shared outside of the CCG unless it is for the purpose of Direct Care, where it may be shared only with those health professionals who have a legitimate relationship with the patient and a legitimate reason to access the data." and asked for this to be removed as it is not relevant to this application. IGARD also noted a number of special conditions in section 6 had been superseded and should be removed; these include the following paragraphs beginning: "Data which has been anonymised in accordance with the ICO Anonymisation Code of Practice"; "Identifiable data will only be disclosed…" and "The Data Protection (Charges and Information) Regulations 2018 require every organisation who processes personal information to pay a data protection fee to the ICO…in this agreement must register with the ICO and paid the appropriate fee by 25th May 2018…". IGARD also noted that the special condition 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. This includes granting of access to the database[s] containing the data." Should also be replicated in section 5. IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 be updated to clearly state that the application privacy notice 'does not' meet the criteria. **Outcome:** Recommendation to defer, pending: 1. To 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. 2. To clearly explain how invoice validation within the application is different from other forms of invoice validation undertaken by CCG's in general. 3. To clarify within section 5 and section 3(b) if any further data minimisation can be undertaken by the applicant. 4. To 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.

	5. To 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. 6. To include as a special condition the final paragraph of section 5(b) "Patient level data will not be shared outside of the data controller…". 7. To 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…". 8. To 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.
2.9	<u>NHS Calderdale CCG: DSfC – NHS Calderdale CCG – STP - Comm (Presenter: James Humphries-Hart) NIC-192032-K0J3X</u> **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows; Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS) and National Cancer Waiting Times Monitoring Data Set (CWT). The CCGs will use the data to provide intelligence to support the commissioning of health services and analyse so that health care provision can be planned to support the needs of the population within the Sustainability and Transformation Partnerships (STP) area. **Discussion:** IGARD noted that information was noted within section 3(b) of the application outlining the data minimisation efforts undertaken by the applicant and asked that further information be outlined in section 5 outlining the data minimisation efforts. IGARD queried what the relationship of Kier Business Services Limited and Dr Foster Limited was with the other Data Processors outlined in the application and asked that this be made clear within section 5 including details of any data that they may have access to. IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 be updated to clearly state that the application privacy notice 'does not' meet the criteria. IGARD noted the special condition in section 6 "Data which has been anonymised in accordance with the ICO Anonymisation Code of Practice* (ICOACoP) will be processed and released by the DSCRO in line with the Data Services for Commissioners (DSfC) agreed processes. If data that is anonymised in accordance with the ICOACoP requires re-identification, disclosure must be made under a separate legal basis and must be acted upon in line with DSfC processes." and asked that the legal basis referred to be clarified. IGARD also noted that the special condition "For clarity, any access by Pulsant, Telecity, Yeadon Community Health Centre and Telstra to data held under this agreement would be considered a breach of the agreement. This includes granting of access to the database[s] containing the data." should be included in section 5. IGARD who holds the contract for Data Processor 2, NHS North of England CSU, as outlined in the application and asked for further clarity. IGARD noted that the abstract states "CCGs also have powers to commission and to conduct, commission or assist the conduct of research…" and asked that "assist the conduct of research" is removed. **Outcome:** recommendation to approve subject to the following conditions:

	1. To provide further information within section 5 of the data minimisation efforts undertaken by the applicant and cross reference this within section 3(b). 2. Giving a clear explanation within section 5 of the application the relationship of Kier Business Services Limited and Dr Foster Limited with the other Data Processors outlined within the application, including any data they may have access to. The following amendments were requested: 1. To 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. 2. To clarify the legal basis within the special condition in section 6 "Data which has been anonymised in accordance with the ICO Anonymisation Code of Practice…". 3. To include within section 5 the special condition outlined in section 6 "For clarity any access by Pulsant, Telecity, Yeadon Community Health Centre and Telstra to data health under this agreement would be a considered a breach of the agreement…". 4. To clearly describe who holds the contract for Data Processor 2 – NHS North of England CSU. 5. To remove from the abstract reference to "assisting with research". It was agreed the conditions be approved OOC by IGARD Members
2.10	University College London (UCL): MR1396 - GALA-5: An Evaluation of the Tolerability and Feasibility of combining 5-Amino-Levulinic Acid (5-ALA) with Carmustine Wafers (Gliadel) in the Surgical Management of Primary Glioblastoma. (Presenter: Kimberley Watson) 03422-Y7Y0Z Earlier applications on the agenda required additional consideration and therefore this application was unable to be considered at this meeting.
2.11	NHS South Devon and Torbay CCG: Joint South Devon & Torbay and NEW Devon CCGs access to pseudo HES data (Presenter: Rachel Farrand) NIC-181880-M8W1T **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data. This request is to support both CCGs in delivering some of their statutory functions, ensuring they are getting maximum value for public money, and enabling them to build upon the commissioning for value project performed by NHS RightCare, which involves drilling down into national level data, from areas either identified by NHS RightCare or other areas as they are discovered on an ad-hoc basis. The application was been previously considered on the 26th July 2018 when IGARD had deferred making a recommendation pending; clarification that the applicant have explored using benchmarking data already in the public domain and if this is not available to explicitly state this; clarification that the applicant has considered using HDIS to access the data they require for the pilot; to clearly explain how they will use the benefits derived from this study to inform CCGs across England; the application should be updated to clarify that NHS South Devon and Torbay CCG and NHS Northern Eastern and Western Devon CCG are Data Controllers who also process data; IGARD suggested that the applicant consider how the benefits of the study will be transferable to other CCG settings or made more widely available. **Discussion:** IGARD thanked the presenter for the work undertaken with the applicant to address the comments made upon previous review. IGARD noted that the abstract states "CCGs also have powers to commission and to conduct, commission or assist the conduct of research…" and asked that "assist the conduct of research" is removed.

	IGARD noted that this was a pilot project to ascertain the possible benefits but queried the lack of outputs and requested further examples of proposed patient and public engagement. IGARD observed that upon renewal a clear and detailed analysis of what has been achieved with the extensive data set (compared to what would have been possible with the previous access to data) would be expected, in order to be transparent for the general public when this was published within NHS Digital's data release. **Outcome:** recommendation to approve for 6 months following receipt of data. The following amendments were requested: 1. To remove from the abstract reference to "assisting with research". The following advice was given: 1. IGARD advised when the application returns, IGARD would expect to see further information with regard to yielded benefits and further real-life examples and a clear and detailed analysis of what has been achieved with this extensive data set as compared to what would been possible with the previous access to data. IGARD advised that they would wish to review this application again when it comes up for renewal
2.12	<u>CRAB Clinical Informatics: HES re-supply CRAB Clinical Informatics (Presenter: Rachel Farrand) NIC-351722-W7D4N</u> Earlier applications on the agenda required additional consideration and therefore this application was unable to be considered at this meeting.
2.13	<u>The University of Manchester: MR1102 - British Association of Dermatologists' Biologic Interventions Register (BADBIR) (Presenter: Kimberley Watson) NIC-147941-XX4JP</u> **Application:** This was an amendment application for identifiable Medical Research Information Service (MRIS) and pseudonymised Hospital Episode Statistics (HES) data to assess whether new biologic or immunomodulator treatments used in the for psoriasis have a greater risk of serious side effects or long-term health problems than established treatments. As psoriasis is a long-term condition requiring lifelong treatment, it is important to establish how these drugs compare to the other treatment options available in terms of safety when used over a period of many years. **Discussion:** IGARD noted that the abstract required a further update to ensure that Article 6 and 9 of the GDPR reflects recent discussions between NHS Digital and IGARD including (but not limited to) reference to the Royal Charter and public interest condition under the DPA 2018. IGARD noted that the identifiers that are sent to NHS Digital were not included within section 5 of the application and asked that these be clearly listed. IGARD queried if any yielded benefits had been generated and suggested that proposed outputs and yielded benefits be included within section 5 in order to be transparent for the general public when this was published within NHS Digital's data release register. IGARD noted that the data retention period noted in the application differed from the indicative DSA expiry date and asked that this be amended to reflect date. IGARD noted that under the 'privacy notice' heading in the abstract, there is reference to the fair processing notice special condition, it was suggested this be removed from the abstract as it was not relevant to this application.

	IGARD noted that there were references within the abstract to “reasonable expectations” and suggested this be replaced with “consent”. IGARD queried if the study’s section 251 support was ongoing and asked for confirmation of this. IGARD noted that the applicant was listed in section 1 of the application as a Data Controller and Data Processor but that this be updated to clearly state that the applicant was a Data Controller who also processed data. IGARD noted that the legislative references within section 3(b) were incorrect and asked that this be updated as appropriate, working with DARS IG. IGARD noted that it was unclear if the funding was still in place 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. IGARD noted that there was conflicting information in the application and supporting documents as to who was accessing the data and what data they are accessing in terms of the consent materials and asked for this to be clarified in section 5. It was noted that the applicant may wish to update their consent materials to clearly state that withdrawing from the project would not affect any future care, to provide clear details of how a participant may withdraw and to provide a clear statement that the University of Manchester has specific authority to access the NHS Digital data **Outcome:** recommendation to approve subject to the following condition(s) 1. To update the abstract of Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including (but not limited to) reference to the Royal Charter and public interest condition under the DPA 2018. 2. To clearly list the identifiers that are sent to NHS Digital. 3. To provide a clearer explanation and further examples of the proposed outputs and yielded benefits within section 5 of the application. The following amendments were requested: 1. To align the data retention period with the indicative DSA expiry date. 2. To remove reference in the abstract to the fair processing notice special condition as it is not relevant to this application. 3. To remove reference in the abstract to “reasonable expectation” and replace with “consent”. 4. To provide evidence that section 251 support is continuing. 5. The application should be updated to clarify that the University of Manchester are a Data Controller who also processes data. 6. To update the legislative references within section 3(b), as appropriate. 7. The application should be amended to confirm that funding is still in place. 8. To provide clarification in section 5 who is accessing the data and what data they are accessing since there is a mismatch with the information provided in certain of the consent materials (for example supporting document 2). The following advice was given: 1. IGARD suggested that the applicant update their consent materials to clearly state that withdrawing from the project will not affect any future care, provide clear details of how a participant may withdraw and to provide a clear statement that the University of Manchester has specific authority to access NHS Digital data It was agreed the conditions be approved OOC by IGARD Members

2.14	University of Bristol: MR1332: The Cleft Collective Project (Presenter: Kimberley Watson) NIC-207953-Q9H2M Earlier applications on the agenda required additional consideration and therefore this application was unable to be considered at this meeting.
3	**AOB** **Quoracy** Following consideration by IGARD members and noting that IGARD membership is now six independent members, it has been agreed with NHS Digital that the in-meeting quoracy will be temporarily reduced to three members (50% of the membership) from the 1st October 2018 to the 31st December 2018, or until membership increases to at least eight.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 28/09/18

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