Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 18 October 2018

Members: Sarah Baalham, Kirsty Irvine (Chair), Eve Sariyiannidou.

In attendance: Dave Cronin, James Humphries-Hart, Dickie Langley, Karen Myers, Vicki Williams.

Apologies: Joanne Bailey, Anomika Bedi, Nicola Fear.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The outcomes of the 11 October 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting. The minutes of the 11 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	The University of Manchester: MR1135 – Manchester self-harm project (MaSH) – Mortality and suicide after self-harm – a cohort study (Presenter: Dave Cronin) NIC-147916-DPQ3Q **Application:** This was a new application for identifiable Medical Research Information (MRIS) data for the MaSH project which follows up on individuals who present to hospital with self-harm to find out what happens to them after they are discharged; to monitor rates of suicide following self harm in Manchester; to investigate risk factors pertinent to the local area; and to input directly into local clinical services and suicide prevention strategies. **Discussion:** NHS Digital noted the application had been updated to reflect the correct legal basis under Article 9 of GDPR which was to reflect both the audit and research part of the project and also to highlight that the multi-centre research would share additional MRIS products under pseudo form. It was agreed that the nature of the application, as presented to IGARD as part of their agenda pack, was essentially unchanged. 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 Manchester legal basis including, but not limited to, reference to the Royal Charter and the correct subsection reference under the Data Protection Act (DPA) 2018. IGARD queried the Data Controllership and the information provided in step 2 of supporting document 6.2, 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 Manchester to the University of Oxford 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 and that this processing is outside the scope of this application. Given the interlinked nature of this application (in particular, the Data Controllership arrangements) with both NIC-147957-4444C and NIC-147907-MLK7R, IGARD made clear that their recommendation in respect of this application would be conditional on recommendations also

	being made in respect of both of those linked applications within a reasonably short period of time. IGARD noted that it was unclear if 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 and provide relevant evidence such as a funding letter. IGARD noted that the identifiers that are sent to NHS Digital were not included within section 5(b) of the application and asked that these be clearly listed ensuring they are aligned with section 251 support. IGARD noted that there was insufficient information of the history of the application and asked that the abstract be updated to accurately reflect this. IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice. **Outcome:** recommended for approval subject to (i) the following conditions being met and (ii) both NIC-147957-4444C and NIC-147907-MLK7R being recommended for approval by IGARD within 2 weeks. 1. To explicitly state in section 5 that where the data flows from the University of Manchester to the University of Oxford 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 and that processing is outside the scope of this application. 2. The application should be amended to confirm that current funding is in place and provide relevant evidence 3. To update section 5(b) to clearly list which identifiers are sent to NHS Digital, to align with s251 support. The following amendments were requested: 1. To update the abstract to give a clear history of the application to date. 2. To update the abstract on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD regarding the University of Manchester legal basis including (but not limited to) reference to the Royal Charter and the correct subsection reference under the DPA 2018. The following advice was given: 1. The applicant should work with NHS Digital on a fair processing notice that does not contain misleading statements and is GDPR compliant. It was agreed the conditions be approved OOC by IGARD Members.
2.2	<u>University of Oxford: MR542 – MRC/BHF Heart Protection Study (Presenter: Dave Cronin) NIC-148069-ZB4GM</u> **Application:** This was a renewal application for identifiable Medical Research Information (MRIS) and identifiable Hospital Episode Statistics (HES) data for a study looking at the overall effects on survival of long-term treatment to prevent heart attacks. **Discussion:** IGARD welcomed the application and noted the importance of the long running study. IGARD noted that the protocol provided, supporting document 4, was over 20 years old and suggested that an updated protocol should be prepared to reflect the research currently being

	undertaken. IGARD was unable to discern a clear legal basis in law within the application and supporting documents for the mortality data that was being requested and requested that this be provided. IGARD noted that the identifiers that are sent to NHS Digital, in relation to the data flows outlined, were not included within the application and asked that these be clearly listed. IGARD noted that there were references in the application to the "10 year follow up" through registries and queried when this will commence and when the 10 years will expire and asked for this to be made explicitly clear. IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice. IGARD noted that information was provided of patient and public facing outcomes achieved already, however suggested that the applicant provide further specific examples of actual or planned patient and public- facing outputs within section 5(c). **Outcome:** Unable to recommend for approval 1. To provide a clear legal basis in law for the mortality data requested under this application. 2. To explicitly list the identifiers sent to and received by NHS Digital, in relation to the data flows under this application. 3. To be explicit when the "10 years follow up" through registries will commence and when the 10 years will end. 4. The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant. 5. To provide specific examples of actual or planned patient and public facing outputs within section 5(c).
2.3	<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 this application had previously been approved with conditions on the 4 October 2018. NHS Digital advised that the application was returning to IGARD to include two additional storage locations which the applicant had asked to be included in the application following its approval on the 4 October 2018. IGARD noted the two new storage locations and asked that section 6, the special conditions and section 5(b) be updated to reflect the two additional storage locations as outlined in the updated application.

	IGARD advised that the outstanding conditions still applied to this application and would be reviewed out of committee. **Outcome:** recommendation to approve subject to the following condition(s) as previously raised on the 4 October 2018: 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". In addition, a further amendment was requested at the meeting on the 11 October 2018: 1. To update section 6, special condition, and section 5(b) with the additional two storage locations outlined in the updated application. It was agreed the conditions be approved OOC by IGARD Members
2.4	<u>University Hospitals Birmingham NHS Foundation Trust: 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 was been previously considered on the 4th October 2018 when IGARD had deferred making a recommendation pending; clarifying 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; providing a data flow diagram clearly noting the actors involved and the legal basis for the flow of data; providing 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; 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.'; to change references from 'non-identifiable' data to 'pseudonymised' data; to amend section 3(c) to note state that patient's objections are not applied due to patient consent; 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"); provide details of any ongoing contact with the cohort; provide further details on the patient and public outcomes facing outputs; provide further information on the role of KiTEC in the project and to confirm their legal status; to update section 4 with the standard wording;

	provide a list of all data linkages within section 5 and to replicate this list and statement within the special conditions. **Discussion:** IGARD noted the application had been updated to reflect most of the comments previously raised but the discussion focussed on resolving some matters still outstanding since the review on 4 October. IGARD noted that the purpose of the application was not clear nor if the application was for the analysis part of the study since the data flow diagram provided suggested that the UHB database was already up and running. IGARD noted that NHS Digital was sending the data to UHB, not KiTEC and that it appeared that UHB was the Data Controller with KiTEC a Data Processor. Although the application noted that it was for the study only with a future application to establish the UHB database and KiTEC was the Data Controller, the supporting documents provided for consideration did not support this point. IGARD queried what the role of KiTEC was in the project as it was still not clear within the application if they were a company or a department within the University and asked for further clarity on their legal status. It was noted reference within the application to a "collaboration" with Guy's and St Thomas' Medical Physics Department and asked for further details on this. IGARD noted that supporting document 5, the data flow diagram, was inconsistent with information provided within the application and asked that the data flow diagram be updated to contain a brief reference to the legal basis for each data flow and that it be consistent with the data flows set out in the application provided. IGARD noted that there were references in the application to 'anonymised' and asked that this be replaced with 'pseudonymised'. IGARD queried if there were any data linkages other than those listed in the application and asked that these are listed within section 5(b) immediately before the statement that there will be no linkages other than as permitted in this agreement. IGARD noted that there were references within section 5(b) to 'the database' and asked that for clarity this be amended to clearly reference the 'commissioning through evaluation database'. IGARD noted that some information was provided of patient and public facing outcomes, however suggested that the applicant provide further examples within section 5 of the application. 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. **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 application is for the analysis of the study only. 2. To provide clarification in section 5 why UHB are not considered a Data Controller 3. To provide 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. 4. To 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. 5. Change references from 'non-identifiable' data to 'pseudonymised' data within section 5. 6. To 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.

	7. To update references within section 5(b) 'the database' to clearly state this is referencing the 'commissioning through evaluation database'. 8. To provide further detail on the patient and public outcome facing outputs. 9. To update the reference in the application to consent being taken, to the past tense.
2.5	University of Sheffield: MR1466 – Life and Bladder Cancer: The Yorkshire Cancer Research Bladder Cancer Patient Reported Outcomes Survey (Longitudinal Study) (Presenter: Dickie Langley) NIC-194387-K3H5K **Application:** This was a new application for Medical Research Information Service (MRIS) list clean for the Life and Bladder Cancer Longitudinal Study. The treatment of bladder cancer can affect the physical, psychological and sexual function of a patient, little is known about the impact of the disease and its treatment upon the overall health related quality of life of individuals. The application was been previously considered on the 30th August 2018 when IGARD were unable to make a formal recommendation as there was not a quorum of members present, however they made the following comments on the application: the consent given by the research subjects in the materials provided appeared to be incompatible with the proposed processing and the applicant may wish to consider seeking section 251 support for the proposed list clean; the applicant should ensure that postal addresses would only be sought for those research participants who elected to provide a postal address when first taking part in the study; to produce a GDPR-compliant privacy notice; to update the abstract with the Article 9 GDPR legal basis and supporting narrative; to update the abstract to clearly state that the legal basis for the cross- sectional cohort is both S251 and GDPR. **Discussion:** IGARD noted that the application was presented for advice on consent materials and that the application had been updated to reflect some of the comments previously raised IGARD noted that limited contact information was provided in the patient information leaflet under the section '*What if I change my mind*' and suggested that at least one alternative method of contact be provided under this heading. IGARD noted that under the section '*What will happen if I take part*' the following sentence *"This means that only people who you interact with as part of your normal care and treatment, or who have a clear basis under the law to know details about you, will have access to your personal information."* is misleading and technical and should be amended to reflect accurate information in accessible language or otherwise be removed from the patient information leaflet. IGARD noted that information under the heading '*Who is organising and funding the study*' was located at the end of the patient information leaflet and suggested that this be moved to the top of the document; and asked for further information to be included on the role of the University of Sheffield, including as Data Controller. IGARD noted that under the heading '*Will my taking part in the study be kept confidential*' the first paragraph *"Yes, your taking part will be kept confidential and will be handled strictly in accordance with the consent that you have given and the 1998 Data Protection Act and General Data Protection Regulation (processing is carried out under Article 6 (1)(e) and Article 9 9(2)(j) of the General Data Protection Regulation) All consent forms will be held securely by the local study team from the Trust to whom you gave consent."* is inaccessible and should be amended to reflect the Data Protection Act 2018, should be explicit about the organisations that will receive identifiers as outlined in the consent material and should provide further accessible information on GDPR.

	IGARD suggested that references to data being 'anonymised' and 'anonymous' in all content materials provided should be updated to say 'pseudonymised'. IGARD noted that the consent form references a different patient information leaflet than the one that was shared with IGARD and asked for further clarification on this. IGARD noted that the point in the consent form, outlining who will have access to identifiable data was misleading and should be amended to reflect specific information provided in the patient information leaflet. IGARD noted that reference to the 'data being stored securely and is covered by the data protection act' is quite vague and suggested this be removed. **Outcome:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed.
2.6	University of Sheffield: NIHR programme grant: The Design, Development, Commissioning and Evaluation of Patient Focussed Vascular Services (Presenter: Dickie Langley) NIC-16274-J8H5T **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data for a study into vascular services, one of the workstreams for this study is looking at current service arrangements which involves the examination of vascular service activity and outcomes, identifying trends and variation in activity and aspects of case mix and outcomes. **Discussion:** IGARD noted that this application was funded by the National Institute for Health Research (NIHR) and asked that evidence be provided of continued NIHR funding. IGARD noted that section 5(b) in the application states "*An expert working group of specialists in general practice, vascular surgery, vascular radiology, nursing and other relevant specialties will be established*." and asked for further clarification in section 5(b) of the working group and how they are involved in the project. IGARD queried how the King's College London Health Technology Assessment (HTA) Centre study, as referred to in the application, relates to the original purpose outlined within the application and asked for further clarity on this. IGARD queried who will be accessing the data and if the individuals accessing the project data were substantive employees or otherwise have appropriate honorary contracts in place and that clarification of this be provided in section 5 of the application. IGARD noted that there was conflicting information in sections 3(a) and 3(b) in relation to the 2014/15 data dataset being requested and asked if this was a duplication or a refresh and suggested this be updated as necessary to reflect the correct information. IGARD queried whether the original processing was continuing and asked that section 5 be updated to reflect this and to clearly outline the progress made over the last 2 years of the project. IGARD noted that there were references in the application to 'anonymised' and asked that this be replaced with 'pseudonymised'. IGARD noted that section 5(c) was difficult to understand and asked this be amended to clearly distinguish between what has happened and what is being proposed, for the lay reader. IGARD suggested that amendments noted by its predecessor DAAG (see NIC-310132-K3Z8B) on the 17 March 2015 be addressed. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide evidence of continued NIHR funding.

	2. To clarify within section 5(b) who is the "expert working group of specialists in general practice, vascular surgery, vascular radiology, nursing and other relevant specialist", and how they are involved in the project. 3. To clarify how the King's College London Health Technology Assessment (HTA) Centre study relates to the original purpose outlined within the application. 4. Clarification within section 5 of the application who is accessing the data and confirmation that the individuals / researchers accessing the project data are substantive employees or have appropriate honorary contract(s) in place. The following amendments were requested: 1. To update Section 3(a) or Section 3(b), as may be necessary, to clarify if the 2014/15 dataset requested is a duplication or a refresh. 2. To update section 5 to be clear that the original processing is continuing and to outline the progress made over the last 2 years of the project. 3. To remove any reference in the application to 'anonymised' and replace with 'pseudonymised'. 4. To amend section 5(c) to distinguish between what has happened and what is proposed, in plain English. 5. To address the amendments suggested by IGARD's predecessor DAAG. It was agreed the conditions be approved OOC by IGARD Members.
2.7	<u>King's College London: Survival and recovery after hip fracture surgery by timing of mobilisation (Presenter: Dickie Langley) NIC-164830-L7L7C</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data to provide information on comorbidities and complications for regression adjustment and subgroup analysis to provide the fact of death at 30 days. The application was been previously considered on the 4th October 2018 when IGARD had been unable to make a recommendation pending; confirmation of the HQIP GDPR legal basis; confirmation that HQIP are authorising the use of data; clarifying who the additional Data Controllers are and to provide fair processing notices which are GDPR compliant; to delete the existing text in section 4 and replace with the standard wording. **Discussion:** IGARD noted that the application had been updated to reflect some of the comments previously made, however IGARD noted that Healthcare Quality Improvement Partnership (HQIP) had not provided evidence in law that public task is the appropriate legal basis particularly in light of documents available in the public domain that state that charities (not covered by the FoI Act) providing public services under contract should be treated in the same way as private contractors. IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice **Outcome:** Unable to recommend for approval 1. HQIP have not provided evidence in law that public task is the appropriate legal basis, particularly in light of documents available in the public domain that state that charities (not covered by the FoI Act) providing public services under contract should be treated in the same way as private contractors.

	The following advice was given: 1. The applicant to provide a fair processing notice and ensure that it is compliant with the notice requirements under the GDPR.
4.	**AOB** None

Independent Group Advising on Releases of Data (IGARD): Out of committee report 12/10/18

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-148056-T6T5Z	Imperial College London	30/08/2018	To provide further clarity with regard to the purpose (particularly, if relevant, how there is any change from the existing purpose), including whether different factors are involved.	OOC by IGARD Members	Quorum of IGARD members	*I am content that the condition is met if the following sentence - amended as necessary so the tense makes sense - from the revised abstract is replicated in section 5 a:* *"The study [are seeking permission to] use the personal identifiers of members of their cohort, including NHS Number and those data that have been corrected by NHS Digital, to enable the Airwaves study to work with Dementia Platform UK (DPUK)."*

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

- None notified to IGARD