Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 26 September 2019

In attendance (IGARD Members): Sarah Baalham, Eve Sariyiannidou, Priscilla McGuire, Geoffrey Schrecker (Deputy Chair).

In attendance (NHS Digital): Dave Cronin, Louise Dunn, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Anomika Bedi, Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Maurice Smith.

Observers: Anna Weaver

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 19th September 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	University of Birmingham: MR785 - PD MED Trial- A randomised assessment of the cost of different classes of drugs for Parkinson's (Presenter: Dave Cronin) NIC-147927-8K193 **Application:** This was an extension application for identifiable Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data; and an amendment to merge two previously separate Data Sharing Agreements (DSA) (NIC-147927-8K193 and NIC-221400-G2Y9T) into a single agreement and permitting to share the HES data with the University of Glasgow. The purpose is for a study looking at hospitalisations and deaths following initial therapies to treat Parkinson's Disease which will hopefully impact the prescribing patterns of UK clinicians, which in turn will improve the treatment of patients. **Discussion:** IGARD had a lengthy discussion on the legal gateway for each of the data flows requested and noted that s.251 support was in place for the HES data; however the consent for the MRIS data that was previously disseminated by the Office of National Statistics (ONS) was now too old to be said to provide a valid legal gateway under the duty of confidence to support the data flows. IGARD therefore advised that s.251 support should be sought for the entire cohort of 1896 participants. IGARD queried the reference in section 5(a) (Objective for Processing) that stated *"A subset of trial data including pseudonymised HES data will be securely transferred…"* and asked for further clarity of what else was included in the subset of trail data and if this was data collected as part of the original trial. IGARD noted the reference in section 5(c) (Specific Outputs Expected) to *"…later disease"* and asked that further clarity was provided outlining the meaning of this. IGARD queried information provided in the yielded benefits in section 5(d) (Benefits) that referred to clinical practice changes and asked that further evidence was provided to support

	this; and to also clarify if the benefits were patients' clinical outcomes, NHS planning and management outcomes or both. IGARD suggested that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of public / patient engagement. **Outcome Summary:** Recommendation to approve the HES data only, subject to: 1. To provide further clarify in section 5(a) what else is included in the *"subset of trial data…"* (other than pseudonymised HES data). 2. To update section 5(c) to provide further clarity of what is meant by "…*later disease*". 3. To update the yielded benefits in section 5(d) to provide further evidence to support the clinical practice changes and to clarify if the benefits are patients' clinical outcomes, NHS planning and management outcomes or both. The following advice was given: 1. IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement. **Outcome Summary:** Unable to recommend for approval for the other dataflows included within the application because of the lack of a legal gateway. 1. Even if the consent was deemed appropriate at the time by ONS, the consent is too old to be said to provide a valid legal gateway under the duty of confidence to support the data flows. IGARD advised that s.251 support should be sought for the entire cohort.
2.2	<u>Carnall Farrar**:** Application for Carnall Farrar to access NHS Digital data, to permit more detailed insights into the needs of the population and the challenges facing the system when shaping clinically and financially sustainable health and social care services across England. (Presenter: Dave Cronin) NIC-243790-Y8K8C</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), Secondary Uses Service (SUS+), Emergency Care Data Set (ECDS), Mental Health Services Data Set (MHSDS) and Mental Health Minimum Data Set (MHMDS) for the purpose of controlling the conditions of data aggregation, perform bench-marking analysis as well as specific demands of the NHS stakeholders, to allow them to make effective decisions based on the most up-to-date information. NHS Digital noted reference within section 5(a) to "*a rolling retention of five years of historical data from 2013/14...*" and that this had been updated to correctly reference "*2014/15*". **Discussion:** IGARD suggested that information provided in paragraphs 1, 2 and 4 of section 5(b) (Processing Activities) that outlined who would access the data, information on the restriction of access and clarification that no attempts would be made to re-identify the data was replicated in section 6 (Special Conditions) as a special condition. IGARD noted the special condition in section 6 that stated *"Data will be deleted on a rolling basis. E.g. the oldest year of data will be securely destroyed within 4 weeks when the next full year is received."* and asked that this was updated to say "*Data will be deleted **after 5 years** on a rolling basis. i.e. the oldest year of data…."*. IGARD noted that section 1 (Abstract) did not have NHS Digital's standard wording on Cloud storage and asked that the section be updated with the current wording; in addition, IGARD asked that this was also added as a special condition in section 6. IGARD queried the volume of data being requested and that the data minimisation column in section 3(b) (Additional Data Access Requested) outlined that the data was to be used for

	analytical purposes although no specific examples were given and it did not align with information provided in section 5. It was also noted that minimal information had been provided in the outputs in section 5(c) (Specific Outputs Expected) and asked that a special condition was added to section 6, stating that a report would be provided to NHS Digital within 12-months that included (but not limited to) how many NHS organisations the applicant was working for as a result of receiving the data; and provide some examples of the work that had been undertaken that demonstrated the requirement for the extent of the data provided under this application including detailed outputs and benefits IGARD queried the reference in section 5(b) to *"Primary users"* and "*secondary users*" and that it should be established that these were all substantive employees of Carnall Farrar. IGARD noted the reference to Carnall Farrar's internal Data Security Committee in section 5(b) and suggested that they may wish to consider independent public and patient involvement as part of this Committee. IGARD advised that they would wish to review this application again when it comes up for renewal. **ACTION:** IGARD Chair and Deputy Chair speak to the Associate Director Data Access and the Caldicott Guardian in respect of organisations seeking national data for modelling and benchmarking and the volume of data requested for achieving this. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To add a special condition in section 6 that replicates information provided in section 5(b) outlining who will access the data, restriction of access and to clarify that no attempts will be made to re-identify the data. *2.* To update the special condition in section 6 from *"Data will be deleted on a rolling basis. e.g….."* to *"Data will be deleted after 5 years on a rolling basis. i.e. the oldest year of data…."* 3. To update section 1 to include NHS Digital's standard wording on Cloud storage and to also add this as a special condition in section 6. 4. To add a special condition in section 6 stating that a report will be provided to NHS Digital in 12-months; including (but not limited to) how many NHS organisations the applicant is working for as a result of receiving this data and examples of work done demonstrating the requirement for the extent of data provided. 5. To clarify within section 5(b) that the *"Primary users"* referred to are all substantive employees of Carnall Farrar. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. 2. IGARD suggested that Carnall Farrar's internal Data Security Committee may wish to consider independent public and patient involvement.
2.3	<u>University of Aberdeen: MR756: Knee Arthroplasty Trial (KAT) (Presenter: Dave Cronin) NIC-322051-S8N9N</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES); and an amendment to add the University of Oxford as a Data Controller. The purpose if for a long-running trial, which started in 1998 to examine the clinical effectiveness and cost-effectiveness of four aspects of knee replacement surgery. In total, 116

	surgeons in 32 UK centres participated in the trial. Between July 1999 and January 2003, 4070 potentially eligible participants were identified and 2352 gave consent and were randomised. NHS Digital advised IGARD that a short-term extension permitting retention for an interim period of 3 months had been submitted to the applicant; however this had not been signed and given that the data has been held with no Agreement in place for such a lengthy period, this application was progressing based on what permissions could be granted; and that should the Agreement not be signed within 1 month of being issued, it would be withdrawn and destruction of the data would be required. NHS Digital advised IGARD that they had requested an audit on this organisation in relation to this application / data sharing agreement (DSA). **Discussion:** IGARD noted the update from NHS Digital on the short-term extension that had been issued to the applicant and had not been signed, and endorsed NHS Digital's assessment that should the Data Sharing Agreement (DSA) not be signed within 1 month of being issued a destruction of the data notice would be issued. IGARD also noted and endorsed NHS Digital's request for an audit on the organisation in relation to this application / data sharing agreement. IGARD had a lengthy discussion on data controllership and the amendment request to include the University of Oxford as a joint Data Controller, noting that the Chief Investigator was a substantive employee of the University of Oxford. Based on the evidence presented to IGARD it was clear that the original consent material did not provide a legal gateway for the University of Oxford to be a Data Controller or to process the data and suggested that the Chief Investigator seek s.251 support from HRA CAG. It was also noted that in supporting document 1, the Protocol, there were a number of other organisations involved in the study. IGARD asked that written justification was provided as to why those organisations were not also considered joint Data Controllers. **Outcome Summary:** recommended to approve for the University of Aberdeen to retain the data for a limited time period of 6 months, but not otherwise process the data by either the University of Aberdeen, or by any other organisation. IGARD supported NHS Digital that if this short-term extension DSA is not signed within 1 month, then a data destruction notice will be issued. The following comments were made: 1. Since the original consent does not provide a legal gateway for the University of Oxford to process the data, the University of Oxford which, based on the evidence presented, is the Chief Investigator and (joint) Data Controller may wish to seek s251 support from HRA CAG. 2. Since a number of organisations are listed within the protocol provided written justification should be provided as to why these organisations are not considered joint Data Controllers. The following advice was given: 1. IGARD noted and endorsed NHS Digital's request for an audit on the organisation in relation to this application / data sharing agreement.
2.4	<u>NHS Sunderland CCG: DSfC - NHS Sunderland CCG - Comm (Presenter: Dickie Langley) NIC-250326-W3F1B</u>

	Application: This was a renewal application for pseudonymised Secondary Uses Service (SUS) for Commissioners, Mental Health Services Data Set (MHSDS), Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Minimum Data Set (MHMDS) data; and an amendment to add Microsoft UK as a Data Processor. The purpose is to provide intelligence to support the commissioning of health services, by understanding the interdependency of care services, targeting care more effectively and using value as the redesign principle. The application was been previously considered on the 31st January 2019 when IGARD had been unable to recommended for approval, pending: IGARD did not have a complete position from NHS Digital with regard to cloud storage in order to confidently acknowledge the risks involved and mitigation taking place; and to update the data flow diagram provided with the pseudonymised GP data as described in the application. NHS Digital advised IGARD that there was an error in supporting document 1, the Data Flow Diagram and that this would be amended to update the name of the pseudo tool used by the Data Services for Commissioners Regional Office (DSCRO) and to update the Civil Registrations data supplied by DSCRO; and that once the dates had been made, NHS Digital's Customer Relationship Management (CRM) system would be updated with the latest version. **Discussion:** IGARD noted that the application had been updated to reflect all of the comments previously made. IGARD noted the update from NHS Digital on the amendment to the data flow diagram and supported the amendments to update the name of the pseudo tool used by DSCRO, to update the Civil Registrations data supplied by DSCRO and the upload a revised version of the document to NHS Digital's CRM system. **Outcome Summary:** recommendation to approve 1. To amend the Data Flow Diagram to update the name of the pseudo tool used by DSCRO and to add the Civil Registrations data supplied by the DSCRO; and to update the CRM holder with the updated version.
2.5	University College London: Centre for Longitudinal Studies Next Steps Data Linkage: Next Steps Age 25 Study (Presenter: Dickie Langley) NIC-51342-V1M5W **Application:** This was an amendment application to include a sub-licensing model to the current Data Sharing Agreement (DSA). The purpose is for a longitudinal study following the lives of 16,000 people to map their journeys through education and transitions into adulthood and the labour market; has already been highly valuable in informing policy decisions and in enhancing understanding of how specific Government policies can influence and shape the lives of young people. NHS Digital advised IGARD that some of the points from NHS Digital's the 'Sub-Licencing and Onward Sharing of Data' Standard (Standard 10) had not been met; **point 3** *"Any request for sub-licencing must be clear in the application and an indication given as to the anticipated volume/number of sub licencees as well as the potential length of the sub licences"*; **point 5d** *"Applicants must provide Information Governance criteria applied by the sub-licence approval group to applications for data"*; **point 5e** *Applicant must provide Detail of legal basis for onward sharing of the data"* and **point 6** *"The applicant must set out in the purpose section the assessment criteria that it will use in determining who to grant sub licences to and on what conditions. For example, the nature and type of sub-licencee should be identified in the application (e.g. research by UK universities only), with an explanation of what sharing is meant to achieve, what information to be shared, who needs access. In general, applicants will need to show that sub licencing will be in the public interest and that that the data will be*

	used either (i) for the provision of health care or adult social care; or (ii) for the promotion of health. Applicants will also need to explain how they will ensure that sub licencees respect and promote the privacy of recipients of health services and of adult social care associated with the data that they receive. **Discussion:** IGARD endorsed NHS Digital's assessment that the application did not meet specific points outlined in the 'Sub-Licencing and Onward Sharing of Data' published standard and asked that the application was amended throughout to address the four points: specifically point 3, point 5d, point 5e and point 6. NHS Digital queried if the information provided on 'sub-licensing' in section 5(a) (Objective for Processing) should be updated to also confirm that there would be no charge for the sub-licensing; IGARD agreed that this update should be included. IGARD queried point 7 under NHS Digital's Fair Processing Assessment in section 1 (Abstract) and asked that this was updated to reflect that the data was being supplied by NHS Digital. IGARD noted that there was a named Member of Parliament referred to in section 5(d) and asked that this was removed and replaced with a more generic statement. **Outcome Summary:** Recommendation to defer, pending: 1. To amend the application throughout to address the following points from the 'Sub-Licencing and Onward Sharing of Data' Standard. a. Point 3: b. Point 5d: c. Point 5e: d. Point 6: 2. To confirm within section 5(a) that there will be no charge for the sub-licensing. 3. To update section 1 to reference that data is being supplied by NHS Digital under the NHS Digital Fair Processing Assessment in point 7. 4. To update section 5(d) to remove reference to the named MP and replace with a more generic statement of use.
2.6	<u>St George's, University of London: Pre-participation screening: Clinical outcomes of a large UK cohort (Presenter: Louise Dunn) NIC-190086-F5Z7B</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) and Civil Registrations data for a study aiming to estimate the incidence of sudden cardiac death and sudden cardiac arrest, in a population of individuals who had previously undergone assessment with pre-participation screening over a ten-year period. This is to assess the value of cardiac screening overall, individual tests used, as well as specific indices of these tests of identifying individuals with conditions predisposing to sudden cardiac death or adverse outcomes (sudden cardiac death, sudden cardiac arrest); and to assess the effectiveness of screening of detecting different conditions predisposing to sudden cardiac death. NHS Digital noted reference to "*linked mortality data*" within section 5(b) and that this had been subsequently updated to include "*HES data*" **Discussion:** IGARD noted information provided in supporting document 1, the Protocol which described Cardiac Risk in the Young (CRY) as the 'Data Custodian' and referred to one of the two investigators as a substantive employee of CRY. IGARD suggested that either written justification was provided as to why CRY were not considered a joint Data Controller; or to include CRY as a joint Data Controller.

	IGARD noted that the data flow outlined in section 1 (Abstract) was inconsistent with the information set out in section 5; and were advised by NHS Digital that the information in section 1 was correct and was consistent with the s.251 support. IGARD asked that section 5 was updated accordingly to reflect the correct data flows, since this section would be published and formed part of the Data Sharing Agreement (DSA). IGARD queried if CRY would only receive aggregated data with small numbers supressed and were advised by NHS Digital that this was correct. IGARD asked that a special condition was added to section 6 to clarify this point. IGARD queried what the process would be in the event that the study identified a high rate of false negatives or false reassurance from the screening and asked that section 5(d) (Benefits) was updated to clarify this and to also outline how this would be communicated to participants. IGARD noted the references in the application to *"young adults"* and asked that the application was updated throughout to correctly reference *"**children and** young adults"*. IGARD also asked that in-light of children forming part of the cohort, that section 5(b) (Processing Activities) was updated to add "*parental consent*" where consent was referred to. IGARD noted that section 5(a) (Objective for Processing) 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 specific examples of public / patient engagement. IGARD noted point 2 under the 'Common Law Duty of Confidentiality' in section 1 (Abstract) which referenced patient engagement and asked that this information was also replicated in section 5(c) (Specific Outcomes Expected). IGARD noted that on the list of identifiers provided in section 1, the *"Date of Death"* should be amended to state *"if applicable"* next to it; and that this should also be replicated in section 5(b). IGARD queried the sentence in the data minimisation column in section 3(b) (Additional Data Access Requested) and asked that this was updated to correctly state *"Only individuals who have undergone cardiac **screening**…".* IGARD queried the information provided in the 'identifiability' column in section 3(b) that stated the data was "identifiable" and asked that in-light of the information provided in the application, that this was amended to Pseudo/anonymised data. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To provide a written justification why CRY is not considered a joint Data Controller, in light of the protocol provided which describes CRY as the Data Custodian and shows one of the two investigators is a substantive employee of CRY, or to include CRY as a joint Data Controller. The following amendments were requested: 1. To update section 5 to reflect the data flow that is correctly outlined in section 1 and in the s.251 support. 2. To add a special condition in section 6 clarifying that CRY will only receive aggregated data with small numbers supressed. 3. To update section 5(d) to clarify the process in the event that the study identifies a high rate of false negative results from the screening and how this will be communicated to participants.

	4. To update the application throughout to ensure references to "young adults" are amended to *"**children and** young adults"*. 5. To amend section 5(b) to add reference to *"parental consent"* where consent is referred to. 6. To provide further details of pathways of dissemination of the outputs including any specific examples of public / patient engagement 7. To amend section 5(c) to include the information noted in section 1 on patient engagement. *8.* To update the data minimisation column in section 3(b) to correctly state *"Only individuals who have undergone cardiac **screening**…".* 9. To amend section 1 and section 5(b) the list of identifiers in section 1 to state that *"Date of Death"* that is part of the identifiers list will flow "*if applicable"*. 10. To amend the data table in section 3(b) to show identifiability as Pseudo/anonymised instead of identifiable. It was agreed the conditions would be approved OOC by IGARD Members.
3	<u>Returning Application - NIC-84216-X2D7K NHS London Healthy Urban Development Unit</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. IGARD welcomed the application as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight & Assurance Report which will be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.
4	**AOB:** There was no further business raised, the IGARD Deputy Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 20/09/19

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-317048-N8P0R -	NHS Midlands and Lancashire CSU	12/09/2019	1. NHS Digital should satisfy themselves that NHS Redditch and Bromsgrove CCG have published transparency material, such as a Privacy Notice.	IGARD Members	OOC by quorum of IGARD Members	
NIC-47221-T6B6Y	NHS Wigan Borough CCG	29/08/2019	1. To revise the application throughout to remove reference to data disseminated and processing already undertaken as part of the applicant's STP application, previously presented to IGARD on 15 March 2018, to ensure that there is no duplication of data being disseminated between this application and the earlier application; and in addition to update the data flow diagram.	IGARD Chair	OOC by IGARD Chair	
NIC-262206-F1P5Z	University of Glasgow	29/08/2019	1. To clarify, in section 5, why the applicant needs patient data with an obstetric episode 5 years after a cardiac episode and why an obstetric episode during a period of, for instance, 1 year after a cardiac episode would not suffice.	IGARD Members	OOC by quorum of IGARD Members	
NIC-120105-F0K2L -	University of Leicester	15/08/2019	1. To clearly explain why the other organisations listed in the protocol and the collaboration agreement are not regarded joint data controllers for the study, as the	IGARD Members	OOC by quorum of IGARD Members	

			study protocol and other supporting documentation do not specify which organisations are involved in each workstream of the study. 2. To provide written evidence that appropriate honorary contracts are in place for the individuals who will carry out the health economics analysis, which will include a clause that the substantive employer of the person under the honorary contract will take disciplinary action in the event of a data protection or confidentiality breach. 3. To provide evidence that the original s251 support is ongoing.			
NIC-161422-Q0K1M	Royal Liverpool University Hospital	11/07/2019	1. To clarify why the University of Liverpool are not considered a joint Data Controller; and why they have been added as a Data Processor. 2. To provide written up to date evidence that ongoing funding is in place. 3. To confirm in section 5 that the collaborators referred to in the protocol are not part of the study team outlined in the application. 4. To provide written evidence of the communication between the applicant and HRA CAG confirming NVR dataset was part of the initial application and is therefore part of the ongoing s251 support.	IGARD Members	OOC by quorum of IGARD Members	

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

- None