Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 19 September 2019

In attendance (IGARD Members): Sarah Baalham (Item 2.4), Maria Clark, Kirsty Irvine (Chair), Eve Sariyiannidou, Maurice Smith.

In attendance (NHS Digital): Dave Cronin, Louise Dunn, James Humphries-Hart, Dickie Langley, Victoria May, Karen Myers.

Not in attendance (IGARD Members): Anomika Bedi, Nicola Fear, Priscilla McGuire, Geoffrey Schrecker.

1	**Declaration of interests:** Maria Clark noted a professional link with the team at the University of Birmingham [NIC-242146-J2W3T) and would not be part of the discussion. It was agreed Maria would not remain in the meeting for the discussion of that application. **Review of previous minutes and actions:** The minutes of the 12th 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	<u>University of Oxford</u>**:** <u>MR461 - A long term follow-up study of Aperts Syndrome (Presenter: Dave Cronin) NIC-148106-PP9LS University of Oxford</u> **Application:** This was an extension application for pseudonymised Medical Research Information Service (MRIS) data for a long-term study that ran from 1994 – 2013 looking at the cause of Apert syndrome, which is a rare malformation syndrome comprising two distinctive features, namely a characteristic appearance of the face and skull due to early closure of the skull bones (craniosynostosis) and bony fusions of the fingers and toes (syndactyly). The application is for the release of the publication and to verify the conclusions published from the study. 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 and endorsed NHS Digital's request for an audit on the organisation in relation to this application / DSA. IGARD also noted that the data was processed for the purpose of pseudonymisation without the appropriate legal basis, however advised that as the present application was for pseudonymised data only, they were content to proceed on that basis. IGARD noted the sentence in section 5(d) (Benefits) that stated *"Apert syndrome is a serious disorder providing many challenges for parents and affected children"* and asked that this was amended to ensure the challenges Apert syndrome provides to children is noted prior to the challenge to the parents. IGARD queried the reference in section 1 (Abstract) to *"archiving"* and were advised by NHS Digital that this was incorrect and would need removing; IGARD asked that section 1 was updated to reflect this amendment.

	IGARD noted that NHS Digital were requesting advice on how a privacy notice could be provided to participants, in light of the applicant or NHS Digital being able to identify them; IGARD suggested that the applicant may wish to consider using the *"Living with Aperts Syndrome"* website already set up and in use to reach participants and their wider families. IGARD also suggested the applicant may also wish to consider liaising with genetic services located within major hospitals in order to reach the extended families of the cohort and/or those with Aperts syndrome. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To amend the sentence in section 5(d) to ensure the "challenges to children" is noted prior to the "challenges to parents". 2. To update section 1 to remove the reference to the applicant "archiving". The following advice was given: 1. IGARD suggested that, in response to the request for advice on how to provide a privacy notice to participants and their wider families, that the applicant may wish to consider using the "Living with Aperts Syndrome" website already set up and in use. 2. IGARD suggested the applicant may also wish to consider liaising with genetic services located within major hospitals in order to reach the extended families of the cohort and/or those with Aperts Syndrome. 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
2.2	<u>Manchester University NHS Foundation Trust: Triage-HF Plus: Cardiac Implantable Electronic Device Remote Monitoring Combined with Telephone Triage to Identify and Manage Worsening Heart Failure (Presenter: Louise Dunn) NIC-204376-Y0V5Y</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) and Civil Registrations data to evaluate the new Triage HF Plus pathway for the remote monitoring of heart failure stability and establish the accuracy of the pathway to predict adverse events and healthcare utilisation. Results will be published in a peer-review medical journal, presented at conferences; and will likely feed into a bigger programme of service improvement by better use of cardiac device remote monitoring systems. **Discussion:** IGARD noted and endorsed the Health Research Authority Confidentiality Advisory Group's (HRA CAG) recommendation in relation to the s251 support. IGARD noted the reference in section 5(a) (Objective for Processing) to an 'Exit Strategy' which stated *"Anonymisation after linkage of data would be the exit strategy."* and queried what this related to, for example was it for this application or longer term; and asked that this was updated with further clarity. IGARD also queried what was meant by *"anonymisation"* and how the Exit Strategy complied with the advice given by HRA CAG to uplift the consent materials and process. IGARD noted that the applicant was relying on consent for the original purpose and also NHS Digital's review that the applicant's privacy notice did not meet NHS Digital's fair processing criteria for privacy notices; and asked that a special condition was included in section 6 (Special Conditions) expictly stating that the applicant was to provide a Privacy Notice that satisfied NHS Digital and was compliant with the General Data Protection Regulation (GDPR) within six weeks of the Data Protection Agreement (DPA) been signed. IGARD also asked that

	the applicant confirm how they would make the Privacy Notice accessible to the cohort and how they will make it available to the cohort, for example via an e-mail, poster in the relevant cardiac clinic waiting rooms etc. IGARD queried if the purpose of the application was research or service evaluation and were advised by NHS Digital that whilst there was an element of research, it was predominantly service evaluation; IGARD asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to ensure that the appropriate Article 9 subsection was referred to (service evaluation) and that any additional amendments that flowed from this were also addressed. IGARD noted the references to Medtronic Inc within the application and asked that section 1 and section 5 were updated with clarification of how Medtronic Inc involvement was addressed both now and in the future. IGARD queried the reference within the application to *"managing patients"* and asked that this was amended to correctly state *"managing conditions"*. IGARD noted the reference in section 5(d) (Benefits) that stated *"…results will be* *restricted to English speaking patients/members of the public"* and asked that the last two sentences were removed as they were not relevant. IGARD queried the wording in section 1 for the NHS Foundation Trust legal basis and asked that this was updated with the most recent wording, along with further clarity of how the Data Protection Act (DPA) was being complied with. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To update section 5(a) to clarify what the 'Exit Strategy' relates to, what the applicant means by 'anonymisation' and how the Exit Strategy complies with the CAG advice to uplift the consent materials and process. The following amendments were requested: 1. To update section 6 to include a special condition to explicitly state that the applicant is to provide a GDPR compliant Privacy Notice that satisfies NHS Digital within 6 weeks of the DPA being signed; to confirm to NHS Digital how they are making the Privacy Notice accessible to the cohort and how they will make it available to the cohort (for example via an e-mail, poster in the relevant cardiac clinic waiting rooms etc). 2. To update section 1 and section 5 to ensure the appropriate Article 9 subsection is referred to (service evaluation) and that the additional amendments flowing from this are also addressed. 3. To update section 1 and section 5 to clarify how Medtronic Inc involvement is addressed both now and in the future. 4. To amend the application throughout to ensure the reference to "managing patients" is amended to "managing conditions". 5. To remove the last two sentences in section 5(d) as they are not relevant. 6. To update section 1 with the most recent wording for the NHS Foundation Trust legal basis and how the DPA is being complied with. It was agreed the condition be approved Out of Committee (OOC) by IGARD Members.
2.3	<u>North West EHealth Limited: Feasibility study: Retrospective data analysis of HES and DID data from patients with Refractory Chronic Cough (RCC) who have given consent for their electronic healthcare records to be used in the analysis of healthcare resource utilisation. (Presenter: Louise Dunn) NIC-290527-P5C0Y</u>

	Application: This was a new application for identifiable Hospital Episode Statistics (HES) and Diagnostic Imaging Dataset (DIDs) data for a feasibility study aiming to increase the understanding of the profile and characteristics of patients with unexplained Refractory Chronic Cough (RCC) by understanding the healthcare resource utilisation (HRU) and treatment patterns of these patients. The primary objective of the initial work is: To determine the outpatient and primary care healthcare costs in the 5-years prior to a diagnosis of RCC, compared to a control cohort, matched by demographics and smoking status. NHS Digital advised IGARD that the information provided in section 1 (Abstract) on the Data Controllers was misleading and that it would be updated to correctly state that Merck Sharp and Dohme Limited and Manchester University NHS Foundation Trust were joint Data Controllers; and that North West EHealth Limited were the applicant and Data Processor acting under the direction of the Data Controllers. **Discussion:** IGARD noted the two updates from NHS Digital in relation to the amendment to section 1 to clarify the correct joint Data Controllers. IGARD also noted the update from NHS Digital on the role of North West EHealth Limited, however queried why they were not also considered a joint Data Controllers, in light of the supporting documents provided, for example supporting document 3, the Protocol; and the reference in the application to a *"partnership"* with the study sponsors; and asked that a written explanation of this was provided. IGARD noted the applicant had selected legitimate interests as a legal basis and suggested that section 5(a) (Objective for Processing) be amended to clearly set out what the legitimate interests were and how they related to the processing. IGARD also asked that further information was provided outlining how the case for the legitimate interest legal basis had been established; and asked that a copy of the Legitimate Interest Assessment (LIA) or significant extracts was provided as part of the review. IGARD queried how the specific outputs and expected benefits will practically realise the legitimate interests described and asked that section 5 (Purpose / Methods / Outputs) was updated to clarify this. IGARD noted that as legitimate interest was being relied upon that the applicant should provide a fair processing notice that was compliant with the notice requirements under the General Data Protection Regulation (GDPR) and suggested that they work with NHS Digital to amend their current privacy notice. IGARD noted the information provided in section 5 was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader; and also queried the reference to *"…the burden of RCC"* and asked that further consideration was given to the patient audience and how this type of language could be perceived. IGARD queried if this application related to the members of the cohort and not the control group and asked that the application was amended throughout; and to also be clear that the second part of the project that would compare the consented patient data to a control group was not part of this application. IGARD noted the references to "feasibility" and "cost-benefit" throughout the application and asked that the applicant updated to ensure consistency. IGARD queried what any future application may cover and asked that the application was updated to clarify this. IGARD noted the reference in section 5(c) (Specific Outputs Expected) that stated *"This study will also allow comparisons of UK patients to US and Europe"* and asked that the applicant

	was clear what the anticipated outputs were for the UK study to enable comparisons to the parallel studies in the US and Europe. **Outcome Summary:** Recommendation to defer, pending: 1. To establish the case for the legitimate interest legal basis. 2. To provide a copy of the Legitimate Interest Assessment (LIA) or significant extracts from this. 3. To amend section 5(a) to clearly set out what the legitimate interests are and how they specifically relate to the processing. 4. To update section 5 to clarify how the specific outputs and expected benefits will practically realise the legitimate interests described. 5. Noting that legitimate interest is being relied upon, the applicant should work with NHS Digital on a fair processing notice that does not contain misleading statements and is GDPR compliant. 6. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience (for example when referring to “burden”). 7. To amend the application throughout to be clear that this application relates to the members of the cohort and not the control group and that the second part of the project that will compare the consented patient data to a control group is not part of this application. 8. To update section 1 to clearly outline the correct Data Controllers. 9. To provide a written explanation why North West EHealth Limited are not considered joint data controllers, in light of the supporting documents provided and the reference in the application to a “partnership” with the study sponsors. 10. To be clear what any future application may cover. 11. To be consistent throughout the application when using the terms “feasibility” and “cost-benefit”. 12. To be clear what the anticipated outputs are for the UK study to as to enable comparisons to the parallel studies in the US and Europe.
2.4	<u>University of Birmingham: Agreement for holding the HES data beyond IQVIA HES-THIN sublicense agreement (Presenter: Louise Dunn) NIC-242146-J2W3T</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data to enable the completion of a variety of epidemiological studies to provide benefits to public health in terms of; health service research, health care evaluation and epidemiology of diseases to better understand their causal pathways. **Discussion:** IGARD noted that the University of Birmingham previously had access to the data requested in this application under sub-licensing conditions facilitated by IQVIA, and queried if the purpose to the study had changed; , and asked that for clarity section 1 (Abstract) and section 5(b) (Processing Activities) were updated to clarify that should the purpose change, this would be subject to an amendment application submitting to NHS Digital and the necessary approval being provided. IGARD also queried what data was already held by IQVIA and asked that section 1 was updated with the background to this. IGARD noted the reference to the Data Protection Act (DPA) 2018 and queried how the conditions of Schedule 8 had been met; and asked that further clarity of this was provided in section 1.

	IGARD noted the sentence in section 5(a) that stated "*Funders have no influence over the outputs disseminated"* and asked this was expanded to also state that they will no influence over the design. **Outcome Summary:** recommendation to approve 1. To update section 1 and section 5 to clarify that any change in purpose to the study will be subject to an amendment application to NHS Digital (and the necessary approvals being provided). 2. To update section 1 to clarify how the schedule 8 DPA 2018 condition has been met. 3. To provide further clarity in section 1 outlining the background to the data already held by IQVIA. 4. To expand the sentence in section 5(a) *"Funders have no influence over the outputs disseminated"* to also confirm they will have no influence over the design.
2.5	<u>NHS West Cheshire CCG: DSfC - NHS West Cheshire CCG, RS (Presenter: James Humphries-Hart) NIC-47238-Y6L3M</u> **Application:** This was a renewal application for identifiable Secondary Uses Service (SUS+) data and an amendment for to the process of Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care. **Discussion:** IGARD noted the applicant should provide a fair processing notice that is compliant with the notice requirements under the General Data Protection Regulation (GDPR) and suggested that they work with NHS Digital to amend their current privacy notice. IGARD noted that the applicant had a Data Protection Impact Assessment (DPIA), however it was not GDPR compliant and asked that this was updated to also include a careful analyses of the activities that were outlined in the application; and what their impact was on the data subjects. IGARD queried at what stages there was profiling, solely automated decision making and automated decision making with human interaction; and asked that the application was updated throughout to clarify this; and to also describe how these types of processing complies with the requirements of the GDPR. IGARD noted that the supporting document 2.1the project context document refers to two phases of the project, and asked for further clarity on whether the application was for both phase 1 and phase 2 of the project; and whether it was proposed that GP practices would have access to the data of the entire CCG population. IGARD noted a discrepancy between the description of activities described within the application and the data flow diagram and asked that they were aligned and updated as necessary to ensure consistency. IGARD noted that the proposed processing outlined in the application included the processing of combined primary and secondary care data by the applicant CCG; and asked that the appropriate legal gateways for these combined purposes was clearly described. IGARD queried who the Data Controllers were, noting there was inconsistent information in the application and supporting documents provided and asked that the application was updated to confirm this. IGARD queried the purpose of the application and asked that section 1 (Abstract) and section 5(a) (Objective for Processing) were updated to clearly outline this.

	Outcome Summary: Recommendation to defer, pending: 1. The applicant should work with NHS Digital on a fair processing notice that does not contain misleading statements and is GDPR compliant. 2. To provide a DPIA that is GDPR compliant that includes a careful analysis of the activities outlined in the application and their impact on data subjects. 3. To update the application throughout to clarify at what stages there is profiling, solely automated decision making and automated decision making with human interaction and to describe how these types of processing complies with the requirements of the GDPR. 4. To clarify whether the application is for both phase 1 and phase 2 of the project, as outlined in the supporting documentation, and whether it is proposed that GP practices will have access to the data of the entire CCG population. 5. As the proposed processing includes the processing of combined primary and secondary care data by the applicant CCG, to clearly describe in the application the appropriate legal gateways for these combined purposes. 6. To update the application to clarify the correct Data Controllers. 7. To align the description of activities described within the application with the data flow diagram provided. 8. To update section 1 and section 5(a) of the application to clearly outline the purpose.
4	Returning Application - NIC-148056-T6T5Z Imperial College London 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 **4.1**	**AOB:** The Future of briefing papers IGARD discussed the future of briefing papers presented to IGARD by NHS Digital, specifically the design of the briefing paper template and the purpose of the templates in ensuring there is no duplication across the system.
4.2	Out of Committee - NIC-161422-Q0K1M - Royal Liverpool University Hospital IGARD discussed the out of committee response for application NIC-161422-Q0K1M - Royal Liverpool University Hospital that was presented at the IGARD meeting on the 11th July 2019. A quorum of IGARD Members confirmed that they were content that the conditions had been met and the application was therefore recommended for approval.
4.3	NIC-185930 NHS South Norfolk CCG IGARD noted that following the 9th May 2019 meeting, when IGARD recommended for approval subject to conditions. The relevant extract is as follows:

	“IGARD were unable to recommend for approval as the outstanding condition had not been met, however NHS Digital may choose to progress this application. The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including (but not limited to) being accessible and transparent, removing misleading or confusing information with regard to consent and the right to object, removing the misleading information with regard to anonymised / pseudonymised data and updating the confusing terminology with regard to the right to object and national opt outs.” NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee. 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 13/09/19

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-238370-G8Z6V NHS Bristol	NHS Bristol, North Somerset and South Gloucestershire CCG	29/08/19	1. To significantly redraft section 5(c) to reflect that national data is being received and to consider questions, but not limited to, how the models would be made available to other CCG's and whether the applicant will be charging for any outputs or sharing the models. 2. To reflect within section 5(d) that national data is being received and to clearly outline the benefits that will have an impact nationally.	IGARD Chair	IGARD Chair	N/A
NIC-195793-R5Y3H - University of Surrey	University of Surrey	20/06/19	3. To provide a written explanation why Kings College London and University of Leiden are not considered joint data controllers, in light of the supporting documents provided. 4. Given the funding involvement and commercial interest of 'Sanofi-Aventis', why this application is not considered in anyway commercial. 5. To provide written evidence that NHS Digital are satisfied that the RCGP has appropriate security and that due diligence regarding security is in place.	IGARD Members	Quorum of IGARD Members	The following amendments were requested: *1. To amend section 1 and section 5(a) to clearly set out what the legitimate interests relied on are and how they relate to the processing; and to update the first paragraph in section 5(a) to provide further detailed information on the legitimate interest – This has been amended.* **It is of course up to NHSD and the applicant as to how they**

						wish to reflect this. They may just wish to review this section once again and consider whether they wish to revise the wording so that while referencing the same content it appears less as if they have copied and pasted the LIA test, the intent being to minimise opportunities for challenge, should those arise for some reason. *2. To insert a special condition in section 6 and for the avoidance of doubt that neither 'Sanofi-Aventis' or 'Apollo Medical Software Solutions' can access the data under this agreement, and further if Kings College London and University of Leiden are not considered joint Data Controllers to include them also.* *The following special condition has been added: Sanofi-Aventis, Apollo Medical Software Solutions, Kings College London or University of Leiden can not access the record level data under this agreement.* **NHSD may wish to double check this wording and the use of the *or* in this**

						sentence and consider whether it should use the word *and* instead. An alternative is to state: The following organisations are not entitled to access the record level data provided under this agreement: Sanofi-Aventis, Apollo Medical Software Solutions, Kings College London and University of Leiden. 3. *Can I confirm that the current system does not permit text under section 5e of the application? From the perspective of public trust and transparency I feel that the explanation of why this not commercial for Sanofi should be in a publicly visible part of the application.* **NHSD may wish to consider this comment and insert suitable text elsewhere in section 5, if section 5e is not published.**
NIC-276970-B8Y4H	The Health Foundation	08/08/19	1. To provide an explanation of how the data has been minimised and how specific datasets and data years are required for each project outlined in section 5; (see for example NHS Digital Standard 3 with regard to how data minimisation should be documented).	IGARD Members	Quorum of IGARD Members	The following amendments were requested: A charity cannot be independent of funding. Charities require funding in one way or other. It may be independent of Government (i.e. not a Government

						agency, and I use a capital G as it is not independent of governance as of course it will be governed by a board of trustees). It can also be independent of any Government funding, but the presenter/client would need to be sure this is the point they are trying to make, as many charities have various, often hundreds of income streams, some of which may be government funded. I would suggest a slight amendment is made to the wording

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

- None