Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 23rd January 2020

In attendance (IGARD Members): Maria Clark, Nicola Fear, Kirsty Irvine (Chair).

In attendance (NHS Digital): Stuart Blake, Victoria Byrne-Watts, Louise Dunn, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Geoffrey Schrecker, Maurice Smith.

Observers: Liz Gaffney (NHS Digital) (2.1-2.3)

1	**Meeting Quoracy:** This meeting was not quorate since it did not have four IGARD members present nor two IGARD Specialist Members in attendance and so was unable to provide 'recommendations' to NHS Digital; but would instead provide feedback as per usual process with a relevant statement of support or advise where a further clarification on key issues was deemed necessary. **Declaration of interests:** Nicola Fear noted a professional link with University of Birmingham [NIC-291863-S9M0X] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 16th January 2020 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 Hospital Southampton NHS Foundation Trust: Fractional Flow Reserve Derived from Computed Tomography Coronary Angiography in the Assessment and Management of Stable Chest Pain: FORECAST TRIAL (Presenter: Louise Dunn) NIC-292087-M7V9Q **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data for the purpose of a study to determine whether in a population of patients presenting to the rapid access chest pain clinic routine FFRct (Non-invasive technique using CT to determine Fractional Flow Reserve) is better in terms of resource utilisation, (i.e. number and cost of investigational procedure, number of hospital visits etc.) when compared to routine clinical investigations recommended by The National Institute for Health and Care Excellence (NICE). The application was been previously considered on the 21st November 2019 when IGARD had deferred pending: to update the application throughout to be clear that where there is reference to a Data Controller, that it is specifies which of the joint Data Controllers it is referring to; to update the application throughout to clearly state which organisation(s) will send identifiers to NHS Digital and which organisation(s) NHS Digital will disseminate the requested data to; to update section 5 to expressly state the name of the Data Processor who will be carrying out the activities referenced; to amend section 5(a) to ensure this is either written in language suitable for a lay reader or to include a lay summary of the study; and to consider replicating the text describing the study provided in the patient information sheet in

	order to achieve this; In reference to the consent materials: i) to update section 3(b) to ensure the data minimisation column is limited only to those members of the cohort who have ticked the 'option 9' box in the various iterations of the consent materials and for whom the additional flagging up form was completed; ii) to amend section 1 to revise the description of the consent material analyses undertaken by NHS Digital to address the point about the cohort numbers; In reference to the patient information sheet: i) to clarify the inconsistencies between the patient information sheet and the application where the patient information sheet states that any data collected by the applicant would not identify the participants personally and that non-identifiable data would be managed by the University of Southampton CTU; ii) to clarify the inconsistencies between the patient information sheet which states that only anonymised data would be collected, stored and analysed and statements in the application that the consent form provided the source of identifiable information for linkage and that the University of Southampton CTU would send identifiers of the participants to NHS Digital (name, date of birth, NHS number); to clarify what (if any) NHS Digital data will be on the Rave Tool and associated server; to clarify what (if any) NHS Digital data Medidata will have access to; to clarify the reference in section 5(a) to the mortality data being excluded in light of the statement in section 5(b) referring *"all cause death"*; to provide further information on the funder, in particular in relation to any participation in the project, if they are simply providing funding or if they have any contractual agreements with the Data Controller. Dependent on the information provided, various aspects of the application may need to be updated including (but not limited to) commercial use and special conditions; to amend the special condition in section 6 to confirm that no NHS Digital record level data will flow to Heartflow Inc, nor will any data flow to the USA or any other third party; to provide confirmation if version 3 of the study protocol has ethics approval. **Discussion:** IGARD noted that the application had been updated to reflect all of the comments previously made. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's fair processing notice criteria for privacy notices. IGARD noted the reference within section 3(b) (Additional Data Access Requested) to a cohort figure of *"1400"* and queried if this was the 'net total' of those members of the cohort who had ticked 'option 9' within the consent materials; or if this referred to the size of the wider group from which the relevant cohort would be drawn; and asked that further clarity was provided in section 3(b). **Outcome Summary:** IGARD made a positive statement and were supportive of the application but were unable to make a formal recommendation as there was not a quorum of members able to comment on the application. The following comments were made: 1. To provide further clarity in section 3(b) if the cohort of *"1400"* is the net total of those who have ticked 'option 9' within the consent materials or the size of the wider group from which the relevant cohort will be drawn.
2.2	<u>IQVIA Solutions UK Limited: Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) secondary care pathway analysis. (Presenter: Louise Dunn) NIC-315134-L9Z6B</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) for the purpose of a study aiming to understand the current treatment pathway and disease burden of patients suffering from nasal polyposis and who undergo a surgical treatment known as nasal polypectomy. The primary objective of the study is to quantify the hospital-based burden of the condition related to chronic rhinosinusitis with nasal polyps (CRSwNP) and the surgical treatment patients undergo in the form of nasal polypectomy. The study will furthermore quantify the initial and subsequent treatment related to hospital

	attendances and admissions that include codes indicative of CRSwNP diagnosis, the co-morbidity and differential care profiles of patient subgroups based on risk groups, and the cost and wider burden of patient hospitalisations. **Discussion:** IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's fair processing notice criteria for privacy notices. IGARD noted the reference within the application to an overarching IQVIA Data Sharing Agreement (DSA) (NIC-373563-N8Z9J) and asked that this was provided as a supporting document; and that a brief summary was provided outlining how the purposes in that application extend to this application, since a portion of the data being used for the purpose in this application was being utilised via that overarching agreement. IGARD also noted that section 3(a) (Data Access Already Given) did not reference the overarching IQVIA application and asked that for audit purposes this was section was updated to clearly outline that this application was using data provided under the other overarching IQVIA DSA (NIC-373563-N8Z9J). IGARD noted that IQVIA were relying on legitimate interest as their legal basis and queried the legitimate interest description provided in section 5(a) (Objective for Processing) and asked that further information was provided outlining how the three limbs of the legitimate interest specifically related to the proposed processing outlined in the application. IGARD noted the information provided in section 5(d) (Benefits) in relation to the benefits and asked that this was updated to provide further clarification as to what extent the research outlined in the application is related to the re-licensing of an existing drug for novel use. IGARD also asked that further information was provided in section 5(d) clarifying what the expected benefits would be of the research, in relation to the novel use of the existing licensed drug. IGARD noted the study outlined in the application and queried how the study would specifically benefit the health and social care system and asked that section 5(d) was updated to clearly outline this. IGARD also queried if the stated benefits outlined were achievable with the data that was would be provided and asked that this was clarified in section 5(b). IGARD queried how patient groups would be involved with the study and asked that further information was added to section 5(c) (Specific Outputs Expected) outlining the involvement and asked for clarification that the outputs would be disseminated to a wide range of relevant patient groups. IGARD queried if funding was ongoing and noted that on the information presented it was clear that the funder was not a data controller, however , IGARD asked that section 5 (purpose / methods / outputs) of the application be updated to state that the funder would not have influence on the outcomes nor suppress any of the findings of the research / study. IGARD asked that the application was updated to reference NHS Digital's published 5e Commercial Purpose Standard; and that the relevant points outlined within the Standard were addressed, particularly that the benefits to the public were proportionately balanced against the commercial benefits to the (commercial) applicant and (commercial) funder. IGARD noted that the statement in section 7 (Approval Considerations) that stated *"Ethics approval is not required because…"* was incomplete and asked that this was updated to complete the sentence. **Outcome Summary:** The application was deferred, IGARD were unable to unable to make a formal recommendation as there was not a quorum of members able to comment on the application

	1. To provide the overarching IQVIA application (NIC-373563-N8Z9J) referred to in the application as a supporting document; and to provide a brief summary of how the purposes outlined in that application extend to this application. 2. To update section 3(a) to clearly outline that this application is using data provided under another DSA (NIC-373563-N8Z9J). 3. To update the legitimate interest description provided in section 5(a) to expressly state **what** the legitimate interest is and how it relates to the proposed processing. ~~4.~~ To update section 5(d) to provide clarification as to what extent the research outlined is related to in the re-licensing of an existing drug for a novel use. 5. To clarify within section 5(d) what the expected benefits will be of the research will be in relation to the novel use of an already existing licenced drug. 6. To update section 5(c) to specifically reference how the patient groups are involved and that the outputs will be disseminated to a wide range of patient groups. 7. To update section 5(d) to be clear how this study will specifically benefit the health and social care system. 8. To revise section 5(d) of the application to clarify that the stated benefits are achievable with the data that is being provided. 9. To confirm within section 5 that the funder will not have influence on the outcomes nor attempt to suppress publication of the research. 10. To ensure there is reference within the application to the NHS Digital published 5e Commercial Purpose Standard; and ensure the relevant points outlined in the Standard are addressed, particularly that the benefits to the public are proportionately balanced against the commercial benefits to the (commercial) applicant and (commercial) funder. 11. To update section 7 to complete the sentence *"Ethics approval is not required because…"*.
2.3	<u>University of York: Modelling Healthcare-Evidence Responsive Behaviours (HERBs) in Doctors: A proof of concept study (Presenter: Louise Dunn) NIC-205466-T2F7N</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) data for the University of York and the General Medical Council (GMC). The aim of the study is to model how responsive different graduate groups of consultants are to the publication of new guidelines regarding the use of drug-eluting stents in percutaneous coronary intervention (PCI). Stents are small mesh tubes inserted to keep arteries open after a procedure called angioplasty (percutaneous coronary intervention, or PCI). Drug-eluting stents have a polymer coating over mesh that emits a drug over time to help keep the blockage from coming back. **Discussion:** IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's fair processing notice criteria for privacy notices. IGARD queried the information provided in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) in relation to the General Data Protection Regulation (GDPR) legal basis in particular IGARD noted that the University of York had listed two different Article 9 legal basis and the General Medical Council had not referenced an Article 6 legal basis; and asked that both section 1 and section 5 be updated to clarify the Article 6 legal basis for the GMC; and note on Article 9 basis for the University of York.

	IGARD queried if the University of York would be storing any of the data requested; and were advised by NHS Digital that they would be processing but **not** holding the data; IGARD asked that section 5 was updated to clearly state this. IGARD queried what the focus of the study was and why the specific stenting procedure that was outlined had been selected; and asked that section 5 was updated to clearly outline why they were looking at this particular procedure. IGARD noted that the application stated that the study was focussing specifically on "consultants" and asked why this specific group had been selected excluding other specialists / doctors; and asked that a further explanation was provided clarifying this in section 1 and section 5. IGARD noted the references within the application to *"guidelines"* and asked that this was updated throughout to ensure that this clearly reflected that these were *"NICE guidelines"*, since IGARD noted that other healthcare settings had different guidelines with differing methods for ensuring dissemination and enforcement such as individual NHS Trusts. IGARD queried the statement in section 5(a) (Objective for Processing) that stated *"The research will be valuable and the potential impact on doctors is very low"* and asked that in light of the information outlined within the application and the findings of the US research referred to, that this was reconsidered, since it may be that the impact on doctors was high dependent on the findings of this research study and how it informs practice and policy. IGARD noted that within section 5(b) (Processing Activities) there was reference to the data being linked; and asked that further explicit details were provided of why the data was being linked; particularly referencing the study protocol (supporting document 3) that outlined the North American study that provided details such as training, gender and ethnicity that should be included in section 5 to give a bigger picture of the overall study. IGARD queried how the study would specifically benefit the health and social care system and asked that section 5(d) (Benefits) was updated to clearly outline this. IGARD noted that a number of ethical issues may be raised from this study and asked that these were acknowledged and addressed within the application, since the application was silent on these. IGARD suggested that, noting the consultant group that would be looked at as part of this study, the applicant may wish to consider involving the British Medical Association (BMA) or other relevant doctor stakeholder group(s). IGARD noted that NHS Digital may wish to consider speaking with NHD Digital's Caldicott Guardian to seek further support and guidance, since he was also a clinician and would be able to provide relevant advice. **Outcome Summary:** The application was deferred, IGARD were unable to unable to make a formal recommendation as there was not a quorum of members able to comment on the application. 1. To update section 1 and section 5 to reflect Article 6 and 9 of GDPR for both the GMC and the University of York (i.e. the GMC requires an Article 6 legal basis and the University of York requires a single Article 9 legal basis). 2. To update section 5 to clearly state that the University of York is processing but **not** holding the data. 3. To clearly outline the focus of the study in section 5 and to clarify why the specific stenting procedure outlined has been selected.

	4. To update the application throughout to ensure that any reference to *"guidelines"* is amended to clearly reflect that these are *"**NICE** guidelines"*. 5. To provide a further explanation clarifying why only *"consultants"* have been selected for this study. 6. To reconsider the statement in section 5(a) that states *"…the potential impact on doctors is very low"*. 7. To provide further explicit details within section 5(b) of the data is being linked, particularly referencing the protocol that provides further details of training, gender and ethnicity. 8. To update section 5(d) clarifying how this study will benefit the health and social care system. 9. To acknowledge and address the ethical issues raised by this study. The following advice was given: 1. IGARD suggested the applicant may wish to consider involving the BMA or other relevant doctor stakeholder group(s).
2.4	University of Birmingham: The BASIL-2 trial: comparing the clinical and cost-effectiveness of revascularisation strategies for severe limb ischaemia (Presenter: Stuart Blake) NIC-291863-S9M0X **Application:** This was a new application for identifiable Hospital Episodes Statistics (HES) and Civil Registrations data for the purpose of a trial that builds on the previous 'BASIL' trial to determine whether a 'vein bypass (VB) first' or a 'best endovascular treatment (BET) first' revascularisation strategy represents the most clinically and cost effective treatment for severe limb ischaemia (SLI) due to below the knee (infra-geniculate) arterial disease. The four trial centres are based in Denmark and Sweden, the rest of the 50 trial hospital sites are located in the UK and the trail currently has a small cohort of 323 individuals recruited within England. NHS Digital advised IGARD that the applicant's DPA expiry date was due to expire on the 30th January 2020 and confirmed that the applicant had been made aware of this. **Discussion:** IGARD noted the update from NHS Digital in relation to the applicant's DPA expiry date and that the applicant had been made aware of this. IGARD also noted that this was a useful and valuable study. IGARD commended the well drafted application that demonstrated careful consideration of the patients and participants involved as well as the benefits that would flow from the trial and that this was a worthwhile well-informed study. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's fair processing notice criteria for privacy notices; however, acknowledged the information provided in the consent materials that clearly outlined how participants could withdraw from the trial. IGARD queried the information outlined in section 1 that stated the data requested was *"only for patients within England"* and asked that this was amended to correctly state **England and Wales**. IGARD suggested that the applicant may wish to consider working with a diabetes related charity to ensure the outputs are disseminated to the wider public.

	Outcome Summary: IGARD made a positive statement and were supportive of the application but unable to make a formal recommendation as there was not a quorum of members able to comment on the application. The following comments were made: 1. To amend section 1 to reflect that the data requested is only for patients within England **and Wales.** The following advice was given: 1. IGARD suggested that the applicant may wish to consider working with a diabetes related charity to ensure the outputs are disseminated to the wider public.
2.5	<u>The Health Foundation: Use of secondary care in England by international immigrants (Presenter: Kimberley Watson) NIC-114819-K5Z6Q</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) Outpatient, HES Critical Care, HES Accident and Emergency, HES Admitted Patient Care, Medical Research Information Service (MRIS) and Civil Registration (death) data. The Health Foundation are requesting that NHS Digital create a cohort of migrants for patients who are aged 15 years and over to HES A&E / OP / APC then to mortality data to compare the utilisation of secondary care in England by international migrants in comparison to the 'non-migrant' population, as well as estimating the cost of utilisation for migrants for each year of registration, from 2004 onwards. This application previously came to IGARD on the 3rd October 2019 for advice on the feasibility of the creation of a cohort for a study by NHS Digital for the applicant, where IGARD made a number of observations and suggestions for further consideration. NHS Digital advised IGARD that the study is not intended to target the healthcare of individuals; and advised that this was also noted within section 1 (Abstract) of the application. **Discussion:** IGARD noted the update from NHS Digital that the study was not intended to target the healthcare of individuals. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's fair processing notice criteria for privacy notices IGARD noted that when the application had previously been presented to IGARD for advice, IGARD suggested that NHS Digital seek further guidance on this application from NHS Digital's Caldicott Guardian. IGARD noted that this had been done, however asked that in order for this application to progress, this returned to the Caldicott Guardian (as suggested in October 2019) and a positive statement of support was provided from the NHS Digital Caldicott Guardian. IGARD queried the purpose of the proposed research and how the outputs derived from the data requested would benefit the health and social care system; and asked that this was clearly defined within section 5(c) (Specific Outputs Expected). IGARD also noted the reference(s) within section 1 (Abstract) to the purpose of the research being *"medical research"* and asked that this was removed since it was not relevant. IGARD queried the rationale behind the work outlined in the application and advised that section 5(a) (Objective for Processing) must start with a rationale behind the work and due to the sensitive nature of the theme needed to be very carefully worded. IGARD also advised that it would be very easy for any result coming out of this work to be used against members of society, further damaging the relationships within many communities; and that it was the responsibility of the researchers to get this right. IGARD therefore asked that section 5(a) was updated with this information, including, but not limited to, reference to *"charging back"* or recovering costs of healthcare for migrants.

	IGARD noted the reference(s) to the similar research that had previously been undertaken and asked for further clarification of the purpose of that research and how this research built on previous research undertaken, and how it linked to health and social care. IGARD noted that a number of ethical issues may be raised from this study and the previous research undertaken and asked that these were acknowledged and addressed within the application. IGARD queried at which point the patient group 'UseMyData' would be involved with the study and asked for further clarity of whether this would be at the start, mid-way through or end of the study. IGARD also asked for further clarity on the patient / public involvement with the project and how this had been utilised in the study design. IGARD noted reference(s) within the application to government / political policy benefit, for example "*Evidence is also needed to help inform Government policy…*" and asked these were reconsidered. IGARD suggested that NHS Digital satisfy itself that the application is designed to elicit genuine benefits to health and social care and not advancing a policy agenda as its main aim. IGARD noted the information provided within section 5(a) that outlined *"the two main priorities for the NHS"* and suggested that it be more beneficial if this was moved to the beginning of section 5(a) in order to set the scene. IGARD queried the following sentence in section 5(a) "*How is migrant behaviour modified when controlled for length of time within the country, ethnicity…*" and asked that further clarity was provided on the specific reference to *"ethnicity".* IGARD also queried the sentence in section 5(a) that stated "*The work will only use the following information to characterise patients…*" and asked that a further definition of this was provided. IGARD noted the information outlined in section 5(a) that described the cohorts and asked that further information was provided outlining how these had been created. IGARD specifically asked that the rationale for group 2 was provided "*Non-international migrants*" and why two sub-groups had been created within this particular group and if they would be analysed separately. IGARD noted that one of the substantive employees accessing the data was a substantive employee of Cambridge University, and asked that further information was provided outlining the role of the University within the study. IGARD suggested that the applicant may wish to consider expanding the stakeholder group(s) involved and that these should be reflective of the patients that are the focus of the study. IGARD suggested the applicant may wish to review the term *"migrant'* throughout the application as it was still not clear if this related to new arrivals awaiting settled status or individuals who were born overseas and were legally settled in the UK with the right to access free NHS healthcare - or some other definition. IGARD offered additional out of committee support to the applicant in respect of this application. **Outcome Summary:** The application was deferred, IGARD were unable to unable to make a formal recommendation as there was not a quorum of members able to comment on the application 1. To provide a positive statement of support from the NHS Digital Caldicott Guardian.

	2. a) To clearly define the purpose of the proposed research, including clarification in section 5(c) of how the outputs derived from the data requested would benefit the health and social care system. b) To remove reference(s) to *"medical research"* in section 1 where this is not relevant. 3. To update section 5(a) with a clear rationale behind the work outlined (including, but not limited to, reference to *"charging back"* or recovering costs of healthcare for migrants). 4. To provide further details of the referenced similar research that has previously been undertaken and outline the purpose of this research and how this research links to the previous research undertaken. 5. To clearly address the moral and ethical issues relating to this study and previous research undertaken. 6. To provide further clarity on the point at which the patient group 'UseMyData' will be involved with the study. 7. To provide further clarity on the patient / public involvement in the project and how this has been utilised in the study design. 8. To remove reference to any government / political policy benefit from the application. 9. To amend section 5(a) to move the section outlining the *"two main priorities for the NHS"* to the beginning of this section. 10. To provide further clarity on the reference in section 5(a) to *"ethnicity"*. 11. To provide further details in section 5(a) of how the cohorts were created, specifically the rational on 'group 2', why they have 2 sub-groups within this and if they are going to be analysed separately. 12. To provide further definition on the reference in section 5(a) to *"characterise patients"*. 13. To provide further information on the role of the University of Cambridge within the study, since the substantive employee involved in the study is an employee of the University. The following advice was given: 1. IGARD suggested that the applicant may wish to consider expanding the stakeholder group(s) involved and that these should be reflective of the patients that are the focus of the study. 2. IGARD suggested the applicant may wish to review the term *"migrant"* throughout the application. IGARD suggested that NHS Digital satisfy itself that the application is designed to elicit genuine benefits to health and social care and not advancing a policy agenda.
3	<u>Returning Applications</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. • NIC-06605-X1L9Z University Hospitals Birmingham NHS Foundation Trust • NIC-09519-D5G0R Methods Analytics Ltd • NIC-156334-711SX University of Cambridge • NIC-213403-P3R8Q NHS Improvement IGARD welcomed the four applications 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 and Assurance Report which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.

4 **4.1**	AOB: Standards and Precedents NHS Digital attended IGARD to discuss with members in general the following Standards and Precedents: • Precedent X - Short-term extensions of DSA's • Precedent 8 - Invoice Validation CCG • Precedent 9 – Commissioning CCG • Precedent X - Amendment to CSU address for Cloud use • Standard X - Use of Public Cloud to store and process data supplied by NHS Digital There was no further business raised, the IGARD 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 17/01/20

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-307462-D6B9M	Royal Surrey County Hospital NHS Foundation Trust	05/12/20	1. To provide written evidence of how the HRA CAG s251 conditions of support have been, and continue to be, met, namely the historic dissent.	IGARD Chair	OOC by IGARD Chair	

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the quarterly Oversight and Assurance Report.