Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 8 August 2019

In attendance (IGARD Members): Maria Clark (Alternate Deputy Chair), Nicola Fear, Priscilla McGuire, Eve Sariyiannidou, Maurice Smith.

In attendance (NHS Digital): Victoria Byrne-Watts, Dave Cronin, James Humphries-Hart, Dickie Langley, Karen Myers, Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Kirsty Irvine (Chair) Geoffrey Schrecker.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 1st August 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	<u>The Health Foundation: Monitoring the quality of healthcare in England (Presenter: Victoria Byrne-Watts) NIC-276970-B8Y4H</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistic (HES) and Civil Registrations data for an in-house programme of analyses to be completed over the course of the next five years. The aim being to produce new insights into quality of patient care; investigate how the quality of care can be improved; and understand the demand for health care in the UK using linked HES data and innovative analytical methods. The overall purpose and benefit of this work is to inform the NHS and policy makers about changes in the characteristics and health needs of patients, factors that drive health care utilisation and health outcomes, and variation in health need, and quality of care. The application was been previously considered on the 13th June 2019 when IGARD had deferred pending: to amend section 1, section 5(a) and section 5(d) 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; to update section 5(d) to link each case project to the specific legitimate interest pursued; to provide an explanation of how the data has been minimised and link each dataset to each project outlined in section 5; to amend section 5(b) to remove reference to the ICO Code of Practice; to update section 7 to correctly reflect that ethics approval is not required; to update section 1 to ensure the number of data years reflects the correct information in section 3(b); to update section 1 to remove the statement *"…that they would reasonably expect the processing and it would not cause unjustified harm.".* **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD queried a point raised previously, on how the data requested had been minimised and asked for a further explanation of how specific datasets and data years were required for each of the projects outlined in section 5 (Purpose / Methods / Outputs), for example as outlined in NHS Digital Standard 3 (Data Minimisation).

	IGARD queried the statement made in section 5(a) (Processing Activities) *"As a charity independent of funding and government, and any other interests, it believes that patients would trust that the organisation uses patients' data solely for the purpose of improving the health service and treatments that patients receive."* and suggested that the tone be amended. IGARD noted the General Data Protection Regulation (GDPR) reference in relation to the HES Civil Registration (Deaths) bridge dataset in section 3(b) (Additional Data Access Requested); and asked for confirmation that this only contained data on deceased people; and if so, that the GDPR reference was amended accordingly, noting that this may not be relevant. IGARD suggested that all acronyms upon first use of the application be fully spelt out and clearly described, as may be necessary for a lay reader. IGARD suggested that the sentence in 5(a) that stated *"The Health Foundation has determined that there are no moral or ethical issues arising from dissemination of data for this purpose."* was removed since it was not relevant. IGARD noted the reference in section 5(a) under Work stream 1 (Monitoring Trends) that stated *"The Health Foundation wish to monitor include changes in disease prevalence and complexity over time"* and queried if the research was looking at all diseases or specific diseases and asked that this was amended to clarify this. **Outcome Summary:** recommendation to approve subject to the following conditions: 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). The following amendments were requested: 1. To amend the reference in section 5(a) to public confidence in charitable organisations. 2. To confirm that the HES Civil Registration (Deaths) bridge dataset only contains data on deceased people; and if so to amend the reference to GDPR in section 3(b) accordingly. 3. IGARD suggested that all acronyms upon first use in the application be defined and further explained, as may be necessary for a lay reader. 4. To remove from section 5(a) reference to '*there are no moral or ethical issues*". 5. To confirm whether the research is looking at all diseases or specific diseases; and amend section 5(a) to reflect this. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.2	<u>University of Glasgow: The epidemiology of peripartum cardiomyopathy in the United Kingdom (Presenter: Dave Cronin) NIC-262206-F1P5Z</u> **Application:** This was a new application for pseudonymised Civil Registration and Hospital Episode Statistics (HES) data for a study aiming to collect data on Peripartum Cardiomyopathy (PPCM), which is a rare pregnancy-related type of heart failure and to describe the epidemiology of the condition in the UK. At present, there is no UK-based information to give to women with the condition or to guide decision-making with regards to their management and future pregnancy risk. The study will form part of a programme of research into the epidemiology of PPCM in the UK and will take the form of a retrospective cohort study with nested case-control study, Given that the condition is rare a period of 29 years is being requested for the HES data.

	Discussion: IGARD queried the role of the applicant and the role of other named individuals detailed within the application and supporting document 1, the protocol, and asked that section 5(a) (Processing Activities) was updated to clearly describe that this application relates to a fellowship that will lead to a PhD for this applicant from the University of Glasgow. IGARD noted that clinicians apply for a fellowship with the output being a PhD and noted that the other individuals noted within the application and protocol may be supervising the PhD but asked for confirmation that all other named individuals within the application and protocol will act in the role of supervisor . IGARD noted the references within the application and supporting document 1.0, the protocol to child mortality and morbidity, and asked for further clarity of how this research will be carried out given the datasets requested in the application would only contain the mothers' data. IGARD suggested that the applicant update the protocol to reflect the information provided in the application such as the storage of the data. IGARD noted than many of the other studies had taken place in South Africa and queried the reference in section 5(a) to similar studies in other countries and "Caucasian" (women) in the UK and asked that this was updated to clarify if the study was looking at all women or women within specific ethnic groups. IGARD noted that the British Heart Foundation (BHF) were funding the study and asked that for clarity a special condition was included in section 6 (Special conditions) explicitly stating that they will have **no** access to the data under this application, with the exception of aggregated reports (as outlined in section 5(c)). IGARD had a lengthy discussion on the amount of data that was being collected and asked that further information and justification was provided, in particularly: in the case of the cohort with PPCM, confirmation as to whether the data was being requested for a follow-up period of 10 years as stated in the protocol, or 29 years, or until the end of life since it was not clear; and to provide an clear justification as to why this volume of data was required; confirmation as to when follow-up data will be collected from, for example first symptom or diagnosis etc; confirmation that data is requested only for women who have been pregnant with a recorded event of heart failure (HF) and cardiomyopathy (CM); and whether there is the intention to follow up these individuals and for what period; and clarification as to how the volume of data requested for the cohort, data to be requested for a control group, as well as any end-of-life follow up, are considered appropriate and necessary processing for the relatively short span of a fellowship project which will lead to a PhD. IGARD queried whether the applicant had **not** considered seeking the consent of women who have experienced PPCM given the rarity of this condition; and in light of the significant lengthy period for which the data is requested; and asked that the applicant clarify if and how it had considered any additional permissions and approvals that may be required especially in the case of end-of-life follow-up. IGARD suggested that the applicant should collaborate with relevant patient groups when producing the Patient Information Leaflet to ensure and that it is written in a language suitable for a lay reader. **Outcome Summary:** Recommendation to defer, pending: 1. To clearly describe in section 5(a) that this application relates to a fellowship that will lead to a PhD for the applicant from the University of Glasgow; and provide confirmation that all other individuals named within the application act in the role of supervisor.

	2. To clarify how research will be carried out on child mortality and morbidity (as referenced in the application / protocol) since the datasets requested only contain the mothers' data. 3. To update section 5(a) to clarify if the study is looking at all women or women within specific ethnic groups. 4. To update section 6 to include a special condition to explicitly state that the British Heart Foundation will have **no** access to the data under this application, with the exception of aggregated reports. 5. To provide further information and justification for the amount of data being collected in particular: • in the case of the cohort with PPCM, confirmation as to whether the data is being requested for a follow-up period of 10 years as stated in the protocol, or 29 years, or until the end of life; and to provide an clear justification as to why this volume of data is required; • confirmation as to when follow-up data will be collected from, for example first symptom or diagnosis etc; • confirmation that data is requested only for women who have been pregnant with a recorded event of heart failure (HF) and cardiomyopathy (CM); and whether there is the intention to follow up these individuals and for what period; • clarification as to how the volume of data requested for the cohort, data to be requested for a control group, as well as any end-of-life follow up, are considered appropriate and necessary processing for the relatively short span of a fellowship project which will lead to a PhD. 6. Provide clarification as to whether the applicant has NOT considered seeking the consent of women who have experienced PPCM given the rarity of this condition; and in light of the significant lengthy period for which the data is requested, the applicant to clarify if and how it has considered any additional permissions and approvals that may be required especially in the case of end-of-life follow-up. The following advice was given: 1. IGARD suggested that the applicant should collaborate with relevant patient groups when producing the Patient Information Leaflet to ensure and that it is written in a language suitable for a lay reader. 2. IGARD suggested that the applicant update the protocol to reflect the information provided in the application such as the storage of the data.
2.3	<u>Royal Surrey County Hospital NHS Foundation Trust: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Victoria Byrne-Watts) NIC-225927-H5J7J</u> **Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) to allow performance to be measured against operational cancer standards, to cover the period from first referral to first definitive treatment for cancer and any additional subsequent treatments; to determine whether the operational standard(s) that apply were met or not for the patient and the accountable provider(s). NHS Digital advised IGARD that other CCG's that form part of the Surrey and Sussex Cancer Alliance had also previously requested the CWT Dataset. **Discussion:** IGARD noted the update from NHS Digital in relation to the other CCGs that form part of the Surrey and Sussex Cancer Alliance previously requesting the CWT Dataset; and asked that further clarification was provided on why the applicant was requesting this Dataset in light of the fact the other CCGs already held this data.

	IGARD noted that since the original briefing note with regard to Cancer Alliances had been presented to IGARD in March 2018 then updated in August 2018, the arrangements in place had significantly changed including Data Controller / Data Processor arrangements. IGARD suggested that NHS Digital provide an updated briefing note to IGARD reflecting current arrangements including the Data Controller / Data Processors, the decision making undertaken and how is making those decisions, the products being produced, the degree of automation undertaken and the different variations of cancer alliances across England. **Action:** NHS Digital to provide an updated briefing paper on the Cancer Alliances. IGARD queried the reference in section 5(a) (Processing Activities) to 'The Fountain Centre' under the heading 'Other Organisations within the Cancer Alliance'; and asked that further clarity was provided outlining who they were and what their role was. IGARD noted that section 1 (Abstract) incorrectly provided the legal basis for the CCG's and asked that this was updated to correctly provide the legal basis for the Royal Surrey County Hospital NHS Foundation Trust. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. The NHS Digital IG Advisor to review the applicant's assessment of Data Controllership and provide clarification to IGARD why the other members of the Cancer Alliance are not also considered joint Data Controllers. 2. To clarify why the applicant has requested CWT on behalf of the Cancer Alliance, since individual CCGs forming part of the same Cancer Alliance had previously requested this dataset. The following amendments were requested: 1. To provide further clarity in section 5(a) of who the Fountain Centre are and what their role is. 2. To update section 1 to provide the correct legal basis for the Royal Surrey County Hospital NHS Foundation Trust. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.4	<u>Northumbria University: An investigation of the cost-effectiveness of GP direct access to diagnostic investigations across the North East and Cumbria. (Presenter: James Humphries-Hart) NIC-158112-L0R5C</u> **Application:** This was a new application for pseudonymised Diagnostic Imaging Dataset (DIDs) for a study aiming to assess how effectively GPs use direct referrals to radiology tests for investigation of suspected cancers in the North East and Cumbria region. Rapid diagnosis of cancers is important for improving survival rates, and for achieving the national aim of a definitive diagnosis within 28 days of initial presentation for 95% of cancer patients by 2020. NHS Digital advised that the legal name of the applicant is the 'University of Northumbria at Newcastle', however the application referenced 'Northumbria University' which is the University's trading name and noted that until the Data Sharing Framework Contract (DSFC) was signed in the University's legal name, no data could be disseminated. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD acknowledged the update from NHS Digital with regard to the legal name and trading name of the University and suggested that confirmation be provided that the DSFC was in place and before any data was disseminated. IGARD queried if the correct 'basis in law' had been listed within section 1 (Abstract) and whether it was section 8 (c) or (d) of the DPA 2018 and asked that section 1 was updated to

	clarify this. IGARD noted that the application referred to "Northumbria University's Vision for 2025" outlining its plans for the future however didn't provide further information outlining how Northumbria University was founded. IGARD noted the comprehensive information provided in supporting document 2a, the updated protocol document and asked that information from this was replicated in section 5(a) (Processing Activities), specifically on the different aspects of the projects and with a clearer description of the organisations involved. IGARD noted that funding was only available until the 31st August 2019; however, queried the date provided of September 2019 for the 'final report of results' being submitted. NHS Digital advised that these dates had changed to 2020 and IGARD asked that written evidence was provided confirming that a no-cost funding extension had been given to cover the full period of the updated 'final report of results' date and that section 5(c) (Specific Outputs Expected) was updated to correctly reference the updated 'final report of results' date and the 'publication' date as advised by NHS Digital. IGARD noted that section 3(b) (Additional Data Access Requested) referred to the 'ICO Code of Practice' and asked that this was removed, as it was not relevant. IGARD advised that they had been unable to directly access some of the information via the web links provided in the application and suggested that the links were tested to ensure they worked correctly and that they accessed the appropriate information. IGARD queried the special condition in section 6 (Special Conditions) that stated *"Northumbria University will allow NHS Digital Auditors view only access…"* and asked that this was amended to provide further clarity on the reference to *"view only access"*. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide confirmation that the applicant's DSFC is in place, and before any data is disseminated. 2. To provide written evidence that a no-cost funding extension has been given up to cover the full period up to the updated 'final report of results' date and to update the application accordingly. The following amendments were requested: 1. To provide further clarity in section 5(a) on the different aspects of the projects and to clearly describe the organisations involved. 2. To update section 3(c) to remove the reference to the ICO Code of Practice. 3. To ensure all links provided in the application directly access the appropriate information. 4. To amend Section 6 to provide further clarity on the reference in the Special Condition to *"view only access".* 5. To update section 5(c) to correctly reference the updated *'final report of results'* date and the *'publication'* date. 6. To update section 1 with the correct legal basis under GDPR; and provide further information on how Northumbria University was founded. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
3	**AOB:**

	There was no further business raised, the IGARD Alternate Deputy Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting. As part of their oversight role, IGARD discussed the following matters: • Commercial Purpose Standard 5e – it was agreed that the Commercial Purpose Standard 5e would be updated to reflect discussions with NHS digital and recirculated to both NHS digital and IGARD for further comments.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 02/08/19

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-206314-N1N7K	Manchester University NHS Foundation Trust	23/05/19	1. To provide an explanation on the rationale that *"Patients must be able to provide written, informed consent in the English language."* and what impact this is deemed to have on the outputs and benefits justification; and to update section 5(c) and outlining the impact of the English language only consent; and to replicate this in section 5(d) along with the benefits.	IGARD Members	Quorum of IGARD Members	N/a
NIC-144761-Y3X9Y	King's College London	25/07/19	1 To make a clear statement in section 5(a) that the applicant is not using or linking any datasets from the local study.	IGARD Chair	IGARD Chair	N/A

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

- None