Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 7th May 2020

In attendance (IGARD Members): Paul Affleck, Maria Clark (Alternate Deputy Chair), Kirsty Irvine (Chair) (Item 4 and 5), Imran Khan, Geoffrey Schrecker, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Catherine Day, Dave Cronin, Louise Dunn, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Nicola Fear.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 30th April 2020 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 A).
2	**Data Applications**
2.1	Market and Opinion Research International Limited: M&ORI Ltd Study of ASCS and SACE datasets for the Representativeness of Adult Social Care Surveys (Presenter: Stuart Blake) NIC-349486-Y3C3L **Application:** This was a new application for a pseudonymised Personal Social Services Adult Social Care Survey (ASCS) and Personal Social Services Survey of Adult Carers in England (SACE) extracts, which are important sources for the Adult Social Care Outcomes Framework (ASCOF) outcome measures, used heavily by the Department for Health and Social Care (DHSC) to inform policy development and service delivery. The aim of the research is to explore and understand which groups are under-represented in the ASCS and the SACE data, identify potential causes, the impact these have on survey estimates, and suggested approaches for how this under-representation can be addressed. **Discussion:** IGARD had a lengthy discussion with regard to how individuals and relevant groups were being engaged with as part of this survey, and specifically asked that confirmation was provided of how the results of the survey data were being fed back to patients and carers and how this was used in a useful and meaningful way. In addition, IGARD also queried how those *"under-represented"* groups were being engaged with, either now or in the future; and asked that further clarification was provided. IGARD also noted the reference to the Social Services User Surveys Group (SSUSG) with whom the findings will be shared, and asked for clarification in section 5(c) (Specific Outputs Expected) if this is a group of service users or users of a group of people who are involved with user surveys, since both social service users and carers would be interested in the findings presented to the Group. IGARD noted the three groups outlined for the survey: those responding, non-responders and those eligible for the survey, and queried what data was being held for each of these groups and where the data came from, and asked that confirmation was provided of this. In addition, if the data was from different sources, that confirmation was provided that this was comparable data and whether there was any representative bias in those data sets.

	IGARD noted the statement in section 6 (Special Conditions) *"Service Users may be able to identify themselves"* and asked that this was updated to either remove the reference or to clarify that that this referred specifically to the Data Analyst(s) who may be analysing the data in which they could identify themselves. IGARD queried the statement in section 7 (Ethics Approval) that stated *"Ethics approval is required and in place"* and asked that this was amended to correctly state that ethics approval was **not** required for this research, and that this has been confirmed by the Health Research Authority. IGARD noted the reference in section 5(b) (Processing Activities) to remote workers and asked that this was updated to clearly state that the remote workers were only permitted to access data as specified from within England / Wales. IGARD queried the references in section 5(a) (Objective for Processing) and section 5(c) to the word "*urgent*" when describing the applicant's request to access the data, and asked that this was removed since it was not relevant. IGARD noted reference to a number of technical phrases and words within the application and suggested that it be updated to ensure that technical language was used only where necessary; and where necessary, that it also had an explanation in language suitable for a lay reader. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide further details of: a) How the result of the survey data is being fed back to patients and carers and how this is used in a useful and meaningful way. b) How those "under-represented" groups are being engaged with either now or in the future. c) To provide clarification in section 5(c) if the Social Services User Survey Group (SSUSG) with whom the data is shared is a group of service users or users of a group of people who are involved with user surveys. 2. In respect of the three groups outlined (those responding, non-responders and those eligible for the survey), to confirm; a) what data is being held for each group and where the data comes from. b) if the data is from different sources, to confirm that this is comparable data and whether there is any representative bias in those data sets. The following amendments were requested: 1. To update section 6 to either remove the reference to *"Service Users may be able to identify themselves"* or to clarify that this refers specifically to the Data Analyst(s). 2. To amend section 7 to correctly state that ethics approval is **not** required and that this has been confirmed by HRA. 3. To update section 5(b) to clarify that remote workers are only permitted to do so within the specified territory of use only. 4. To amend section 5(a) and 5(c) to remove the reference to *"urgent"* as it is not relevant. 5. To update the application to ensure the use of technical jargon is used only where necessary; and where it is necessary, to be also written in language suitable for a lay reader. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.

2.2	Northgate Public Services (UK) Limited: NIC-321226-T4B8S Renewal (Presenter: Louise Dunn) NIC-321226-T4B8S **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data; and an amendment to 1) remove Sunguard as a Storage Location; 2) remove Iron Mountain as a Data Processor, 3) to add Gyron Internet Ltd as Data Processor and a Processing / Storage Location, and 4) to add NHS England as Joint Data Controller. The National Clinical Audit and Outcomes Programme (NCAPOP) is a large programme of circa 35 projects consisting of National Clinical Audits. NHS Digital noted that an incorrect reference to "*psychosis*" had been included in section 5(a) (Objective for Processing) and advised that this had now been removed. **Discussion:** IGARD noted the update from NHS Digital on the amendment to section 5(a) to remove the reference to *"psychosis"*. IGARD queried if the "Best Practice Tariff" that NHS Trusts would be reporting against, related to the proportion of patients where there was an unknown consent status, and that clarity was provided confirming this. IGARD noted that section 1(b) (Data Controller(s)) stated that there was a "sole Data Controller" and asked that this was amended to correctly state that there was "joint" Data Controllership. IGARD queried why there was no data in section 3(b) (Data Access Already Given) and were advised by NHS Digital that historical data held by the applicant under this Data Sharing Agreement (DSA) had now been destroyed and therefore information from this section had been removed to reflect this. IGARD asked that section 5 (Purpose / Methods / Outputs) was updated to confirm the historical flows of NHS Digital data that were approved for the applicant and that had now been destroyed. IGARD noted the reference in section 5(a) to the *"fifth 'cleaned' annual data file"* and asked that confirmation was provided that this was included with the dissemination of the 4th quarter data report or if it is a separate additional dissemination of data. IGARD queried the reference in section 5(d) (Benefits) to *"data missing from the NJR has been added retrospectively"* and asked that this was removed as it was not relevant. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **ACTION:** IGARD noted that the Data Controllers had cited different Article 9 GDPR legal bases and noted that on the Information Commissioner's Office (ICO) website that this was possible where there was more than one purpose outlined and agreed that separate to this application this would be discussed in more detail at a future IGARD meeting. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To provide clarification that the Best Practice Tariff target relates to the proportion of patients where there is an unknown consent status. 2. To amend section 1(b) to correctly state that there is *"joint"* Data Controllership. 3. To update Section 5 to confirm the historical flows of NHS Digital data that were approved and that have now been destroyed. 4. To provide confirmation that the *"fifth 'cleaned' annual data file"* is included with the quarter-4 data report.

	5. To update section 5(d) to remove the statement *"data missing from the NJR has been added retrospectively"*.
2.3	Northgate Public Services (UK) Limited: National Joint Registry Annual Extract 2020 (Presenter: Louise Dunn) NIC-07289-G8J6C **Application:** This was a renewal application for identifiable Hospital Episode Statistics (HES) data, Patient Reported Outcome Measure(s) (PROMs) and Civil Registrations data; and an amendment to 1) add NHS England as a joint Data Controller, 2) remove Sunguard as a Storage Location, 3) to add Gyron Internet Ltd as Data Processor and a Processing / Storage Location, 4) to remove Iron Mountain as Data Processor and Processing Location. The National Clinical Audit and Outcomes Programme (NCAPOP) is a large programme of circa 35 projects consisting of National Clinical Audits. The application was been previously considered on the 9th November 2017 when IGARD had deferred pending: section five of the application must include a clearer explanation of why the applicant requires identifiable data for individuals who have not consented, with this accurately reflecting the explanation provided for the applicant's section 251 support to ensure the full purpose is covered by the legal basis; the abstract should be updated to refer to the additional section 251 documentation provided as evidence of legal basis; confirmation that the application includes a statement that Isle of Man data will be sourced elsewhere; the processing activities section should be updated to clarify that the data previously provided to the applicant has been destroyed as this did not have patient objections applied, and therefore data will be resupplied with objections applied. NHS Digital advised IGARD that following IGARD's recommendation to defer this application at the last review on the 9th November 2017, NHS Digital had taken the decision to approve the dissemination of data, the IGARD Chair (at the time) had been informed and this had been noted in the minutes of the 16th November 2017. NHS Digital also advised that the applicant's s251 annual review, which expired in February 2020, had been submitted to the Health Research Authority Confidentiality Advisory Group (HRA CAG) in 2019, and the applicant was currently waiting for this to be approved / published on the HRA CAG Register. **Discussion:** IGARD noted the update from NHS Digital in relation to NHS Digital's previous decision to disseminate the NHS Digital data following IGARD's review; and the current position with the s251 annual review. IGARD also noted that the application had been updated to reflect some of the comments previously made. IGARD queried the *"patient safety"* purpose that was provided as a justification for receiving patient identifiers for those patients who have declined consent for the National Joint Registry (NJR) to hold their personal identifiers; and asked that confirmation was provided on whether this was 'general' patient safety or only for patients where there was a specific and clear issue with regards to patient safety. In addition, IGARD also asked for further clarity of how this issue had been dealt with by the Health Research Authority Confidentiality Advisory Group (HRA CAG) and that confirmation be provided of which supporting document covered the legal basis for this. IGARD queried why, given the updated consent materials provided, the applicant was continuing to rely on s251 for the linkage of data to NHS Digital and in addition why the updated consent did not address the linkage for those patients consenting to participate in the

	NJR, with reliance on s251 only for those individuals where they had not been able to obtain consent. IGARD asked for further clarity on these specific queries. IGARD also noted that consent materials dated February 2020 had been published on the study website but not provided as part of the application pack, and asked that confirmation was provided that the applicant had addressed the opt out issues raised by the Patient Information Advisory Group (PIAG), and if this has been addressed, how they have complied. In addition, IGARD asked that the updated February 2020 consent materials be provided. IGARD noted that supporting document 23, the s251 annual review form, specifically referred to an initial condition of approval referencing the linkage of data, and that this was now not taking place. This had been confirmed in a letter by HRA CAG on the 5th February 2019 And IGARD asked that a copy of this letter was provided, or if the letter was not available, to provide a copy of the annual review or confirmation of its submission to HRA CAG by way of an email. IGARD queried the information in supporting document 1, the Data Flow Diagram, with regard to the flow of data to other third parties via sub-licensing arrangements and were advised by NHS Digital that this Data Sharing Agreement (DSA) did not permit the sharing of NHS Digital data via sub-licensing and that any such amendment in the future would also require the support of HRA CAG. IGARD asked that confirmation was provided within the application that there are no sub-licenses permitted under this DSA, in light of the information provided in the supporting documents and clarify this within section 5(a) (Objective for Processing). In addition, IGARD also asked that the Data Flow Diagram was updated to include the analyses of the cohorts and tasks, and the legal basis for the individual streams in order to better describe the data flows. IGARD noted the role of the University of Bristol as a Data Processor and asked that confirmation was provided that they had destroyed all historical data and had provided data destruction certificates. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that the applicant may wish to consider whether a rolling data set would be more appropriate rather than chunks of data, via numerous applications. **Outcome Summary:** Recommendation to defer, pending: 1. In relation to patient safety: a) To confirm if this is referring to 'general' patient safety for all patients **or** patient safety specific to individuals. b) To provide clarification of how this issue was dealt with by HRA CAG and which of the supporting documents covers the legal basis for this. 2. To provide a copy of the HRA CAG letter dated the 5th February 2019, which confirms the initial condition of approval referencing the linkage of data is not now taking place or, if this letter is not available, to provide a copy of the annual review or confirmation of its submission to HRA CAG by way of an email. 3. To provide confirmation within the application that there are no sub-licenses permitted under this DSA, in light of the information provided in the supporting documents and clarify this within section 5(a) of application. 4. To provide a copy of the February 2020 consent materials as published on the study website and provide confirmation that the applicant has addressed the opt out issue raised by PIAG, and if addressed how they have complied. 5. To provide confirmation that the University of Bristol has destroyed all historical data and provided data destruction certificates.

	6. To explain why, given the updated consent the applicant is continuing to rely on s251 for the linkage of data to NHS Digital and why the updated consent did not address the linkage for those patients consenting to participate in the NJR ,with reliance on s251 only for those individuals where they have not been able to obtain consent. 7. To provide the analyses of the cohorts and tasks, and the legal basis for the individual streams and to update the Data Flow Diagram to reflect this information. The following advice was given: 1. IGARD suggested whether the applicant may wish to consider whether a rolling data set would be more appropriate rather than chunks of data, via numerous applications.
2.4	<u>Health and Social Care Information Centre: National Gastro Intestinal Cancer Audit comprising MR1368 National Bowel Cancer Audit and MR1281 National Oesophago-Gastric Cancer Audit (Presenter: Louise Dunn) NIC-376603-K2J9R</u> **Application:** This was a renewal application for identifiable Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data for a further three years; and an amendment to request additional identifiable Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) for the Bowel Cancer Audit only. In addition, both audits are requesting unlinked (i.e. not linked to the audit data) HES data to support a review of the effect of COVID-19 on the HES cohort of patients in both audits. The National Gastro-Intestinal Cancer Audit Programme ("the GI Cancer audit") comprises both the National Bowel Cancer Audit and the National Oesophago-Gastric Cancer Audit which were previously managed as two separate audits. The aim of the National Bowel Cancer Audit is to assess the quality of care received by patients with bowel cancer in England and Wales. Similarly, the aim of the Oesophago-gastric Cancer Audit is to assess the quality of care received by patients with oesophago-gastric cancer or oesophageal high-grade dysplasia (a pre-cancerous condition) in England and Wales. The application was been previously considered on the 6th December 2018 when IGARD had been unable to recommend for approval pending: HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis; to include within section 5 that as well as the audit resulting in efficiencies for staff, consideration has been given to the needs of patients including whether there is any less intrusive way to process the data; to provide a very brief and simple introduction to section 5(a) to aid the lay reader; to explain within section 5(b) that NELA is just for the bowel cancer audit; to update the abstract to correctly reference the legal basis. NHS Digital advised IGARD that section 3(b) (Additional Data Access Requested) stated the HES Accident and Emergency data and the HES Outpatient data was requested from 2013, however confirmed that this was an error and should state 2011, and confirmed that the application was in the process of being updated to reflect this. **Discussion:** IGARD noted the update from NHS Digital that HES Accident and Emergency data and the HES Outpatient data was requested from 2011 not 2013. IGARD also noted that the application had been updated to reflect all of the comments previously made. IGARD noted the references within the application to the *"Health and Social Care Information Centre"* (HSCIC) and asked that for clarity and to avoid any confusion, section 1 (Abstract) and Section 5 (Purpose / Methods / Outputs) were updated to include a brief statement confirming that the legal entity was HSCIC trading as *"NHS Digital"*; and in addition, to subsequently and

	where deemed relevant, to amend the application throughout to change any references from HSCIC to NHS Digital. IGARD queried if the national data opt outs applied to all the data, noting the conflicting information on this in the patient information sheet and on the website, and asked that confirmation was provided within the application that national data opt outs applied to **all** data. IGARD queried the justification provided in section 1 for the additional data required in relation to the COVID-19 work and reference to "*immediate benefit*", and asked that this was amended to *"support changes to **short term services**".* IGARD also suggested that the applicant may wish to consider requesting further relevant data and that consideration should be given as to how any additional data could be useful in relation to COVID-19. IGARD noted the links within the application to the surgical outcomes data on the website were not working and asked that these were corrected to ensure they were accessible. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that NHS Digital may wish to consider reviewing **all** Privacy Notices for those involved with the audits, not just the Data Controllers, since patients may visit the relevant website of the study rather than the Data Controller websites. Separate to this application, IGARD advised NHS Digital that they may be able to assist applicants who required urgent Health Research Authority Confidentiality Advisory Group (HRA CAG) support in order to obtain NHS Digital data for the purpose of COVID-19 specific applications, and that any requests for support should be sent to the IGARD Chair via the IGARD Secretariat. **Outcome Summary:** recommendation to approve. The following amendments were requested: 1. To update section 1 and section 5 to include a brief statement confirming that the legal entity of the applicant is *"HSCIC"* who are trading as *"NHS Digital"*; and to subsequently and where deemed relevant, to amend the application throughout to change any references from HSCIC to NHS Digital. 2. To confirm within the application that the national data opt outs apply to **all** data. 3. To amend section 1 to refer to *"short term services"* when providing a justification for the additional data in relation to the COVID-19 work. 4. To correct the links with the application to the surgical outcomes data on the website to ensure they are accessible. The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider reviewing all Privacy Notices for those involved with the audits, not just the Data Controllers. 2. IGARD suggested that the applicant may wish to consider further data and to consider how the additional data would be useful in relation to COVID-19.
2.5	<u>University College London: Variation in Healthy Life Expectancy Throughout Childhood and Adulthood in England (Presenter: Catherine Day) NIC-06527-J1Q6T</u> **Application:** This was an extension application for pseudonymised Hospital Episode Statistics (HES) data; and an amendment application to 1) add up to eight University College London PhD students to allow them access to the data, and 2) to update the processing and storage locations. The purpose is to support four studies on variation in healthy life expectancy

	throughout childhood and adulthood in England. This programme proposes 4 clinically relevant research studies investigating the relationship between age at which people develop morbidities or disability requiring hospital admission and subsequent survival. **Discussion:** IGARD noted that section 5(a) (Objective for Processing) included information on the data minimisation being undertaken, however the language used was quite technical. IGARD asked that this was updated further to include additional information on the data minimisation efforts undertaken and that this was clearly explained in a way that was suitable for a lay audience. In addition, IGARD queried what data minimisation had been undertaken for both the Programme and the Projects outlined in the application, and asked that section 5(a) was updated to specifically outline what had been applied to the programme and projects. IGARD queried the reference(s) in section 5(a) that stated *"Minimal research has examined interactions between ethnicity and social deprivation…"* and asked that this was reviewed and that justification was provided with regard to this statement, and that consideration was given as to whether this was in fact a lack of recent research. IGARD queried the reference in section 5(b) (Processing Activities) to a specifically named individual and asked that this was revised since it was not appropriate to name an individual within a Data Sharing Agreement (DSA), and that consideration was given to replacing this with *a specific named role*. IGARD noted that the acronym "CLARHC" had been replaced with "ARC", however there were still references within the application to the original acronym, and asked that the application was revised to ensure the correct use of these acronyms throughout. A number of other acronyms were noted throughout the application, and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use, be clearly defined and that it also had a further supportive explanation in language suitable for a lay reader. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. In relation to Data Minimisation: a) To update section 5(a) to include additional information on the data minimisation efforts undertaken that is explained in a way that is suitable for a lay audience b) To update section 5(a) to specifically outline the data minimisation that has been undertaken for both the Programme and the Projects and what has been applied. 2. To review and justify the reference within section 5(a) regarding minimal research on social deprivation and ethnicity and consider whether this is in fact a lack of recent research. 3. To revise the reference in section 5(b) to a *"specific named individual"* and consider replacing this with a "*role based title*". 4. To revise the application to ensure the correct use of the acronyms *"CLARHC"* and *"ARC"* are used consistently throughout the application. 5. To ensure the use of technical jargon is used only where necessary throughout the application; and where it is necessary, to be also written in language suitable for a lay reader.
2.6	University of Cambridge: MR1417 - ADDITION-Plus study: Ten year follow-up of a randomised controlled trial of an individually-tailored behaviour change intervention among people with

	recently diagnosed type 2 diabetes under intensive UK general practice care (Presenter: Kimberley Watson) NIC-34907-D9R3N **Application:** This was an extension application for identifiable Medical Research Information Service (MRIS) List Clean Report' and an amendment for 1) to request Hospital Episode Statistics (HES) data for 239 participants for the ADDITION-plus study; and 2) a request to use the HES data disseminated under Data Sharing Agreement NIC-28744 for the purpose of the ADDITION-plus study. The Anglo-Danish-Dutch Study of Intensive Treatment In People with Screen Detected Diabetes in Primary Care (ADDITION) studies were created to evaluate whether population-based screening for undiagnosed type 2 diabetes was feasible in a primary care setting; to assess whether subsequent optimised intensive treatment of diabetes and associated risk factors among screen detected patients were feasible in primary care and benefited the patients, and to quantify the harms associated with screening. The ADDITION Plus is a study involving patients within the intensive treatment programme of the ADDITION study in Cambridge, and of patients with diabetes recently diagnosed by their doctor in general practices in Cambridge and surrounding counties. This study aims to collect follow up information on cardiovascular events and risk factors, treatment and mortality for the cohort of participants of the ADDITION-plus study who enrolled in the UK to contribute to ten and fifteen year follow-up work. **Discussion:** IGARD noted that that the last newsletter was issued to members of the cohort in Spring 2016, and that it was not consistently clear within the patient information materials what data was flowing, what data was being linked and how patients were able to opt out of the study. IGARD asked that a special condition was inserted into section 6 (Special Conditions) that the applicant would produce and distribute an updated newsletter detailing what data was flowing, what data was being linked and outlining the ability for the cohort to opt-out and that this was done within 6-months of signing the Data Sharing Agreement (DSA). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** recommendation to approve The following amendments were requested: 1. To insert a special condition in section 6 that the applicant will produce and distribute an updated newsletter detailing what data is flowing, what data is being linked and outlining the ability to opt-out and within 6-months of signing the DSA.
2.7	Care Quality Commission: CQC agreement for HES, MHSDS, MSDS, CSDS and ECDS and associated datasets (Presenter: Dave Cronin) NIC-359603-D2Q6M **Application:** This was an extension and renewal application for identifiable Hospital Episode Statistics (HES), Civil Registrations (CR), Emergency Care Data Set (ECDS), Maternity Services Data Set (MSDS), Mental Health Services Data Set (MHSDS), Mental Health Learning Disability Data Set (MHLDDS) and Community Services Data Set (CSDS) data; and an amendment to add Microsoft Azure as a Data Processor and new Processing / Storage location. CQC's remit is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and CQC encourages them to improve. It does that through effective monitoring and inspection activity underpinned by an Intelligence insight programme that draws together risk and bench marking metrics at core service level. The data directly influence the risk and benchmarking models and help determine both when

	inspections take place and where they should focus. They also help with CQC's statutory responsibility to monitor the use of the Mental Health Act. NHS Digital advised IGARD that this application would be returning to IGARD at some point in the future and would include further details of data destruction. **Discussion:** IGARD noted the update from NHS Digital on a future application returning to IGARD for review. In addition, IGARD noted the special condition in section 6 (Special Conditions) in relation to data transfer and asked that this was amended to state that once the data transfer had been completed, that confirmation of destruction was to include all backup copies. IGARD noted the role of Cap Gemini outlined in section 5(a) (Objective for Processing) with regard to transferring the data from the current storage location to the Microsoft Azure platform, and asked that advice was sought from NHS Digital's Security Team to clarify why Cap Gemini were not considered a Data Processor, or in the event that they were considered a Data Processor to add them to the Data Sharing Agreement (DSA) and to update the application accordingly to reflect this amendment. IGARD queried why the applicant's Data Protection Impact Assessment (DPIA) had not been submitted with the application and supporting papers for IGARD to review, noting that following the last review by IGARD on the 4th July 2019, where IGARD recommended the application for approval, the DPIA was discussed. IGARD therefore asked that a special condition was inserted in section 6 (Special Conditions) that a copy of the DPIA would be provided to NHS Digital within 3-months of signing the DSA. A number acronyms were noted throughout the application, and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use, be clearly defined and that it also had a further supportive explanation in language suitable for a lay reader. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that the applicant should work with NHS Digital to update their Privacy Notice to ensure it was General Data Protection Regulation (GDPR) compliant including (but not limited) to ensuring that the lawful basis was clearly referenced. **Outcome:** recommendation to approve subject to the following condition. 1. To take advice from NHS Digital Security and subsequently either clarify why Cap Gemini are not considered a Data Processor or in the event that they are considered a Data Processor to add them to the DSA and amend the application accordingly. The following amendments were requested: 1. To insert a special condition in section 6 that a copy of the Data Protection Impact Assessment (DPIA) will be provided to NHS Digital within 3 months. 2. To amend the application throughout to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader. 3. To amend the special condition in section 6 that once the data transfer has been completed, confirmation of destruction is to include all backup copies also. The following advice was given: 1. IGARD suggested that the applicant should work with NHS Digital to update their Privacy Notice to ensure it is GDPR compliant including (but not limited to) ensuring that the lawful basis is clearly referenced. It was agreed the condition would be approved Out of Committee (OOC) by the IGARD Chair.

3	Returning Applications 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-195235-Q0B5T University of East Anglia • NIC-18798-V2J6C NHS England (Quarry House) • NIC-156412-Q79WM University of Birmingham IGARD welcomed the three 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. Moving forward, IGARD agreed that COVID-19 and COPI regulation applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and COPI regulation urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 5th May 2020 can be found attached to these minutes as Appendix B. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
5	AOB: There was no further business raised, the Alternate Deputy IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 01/05/20

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-26646-M9Q0J	2020 Delivery	23/04/2020	1. To confirm that the stated outputs are achievable without linking the data that is being provided to any other data sets or qualitative information. 2. To update the data minimisation column in section 3(b) to reflect that the data requested is only for the cohort of those high intensity users attending A&E five or more times in 2015/2016.	IGARD Chair	IGARD Chair	N/A
NIC-267223-D4Q3F	Swansea University	12/12/2020	1. To provide a satisfactory explanation in section 5 confirming that the data requested under this application is sufficiently detailed and robust and will be able to produce the stated outputs; in particular will be able to accurately capture all of the GP models that are being studied (e.g. co-located versus embedded) and how (for example) patients admitted under each model will be recorded in the data sets requested.	Quorum of IGARD members including one medical specialist member	Quorum of IGARD members – in addition to two medical specialist members.	N/A
NIC-58603-S6Z1B	London School of Hygiene and Tropical Medicine	05/12/2020	1. To provide a written transparency plan, detailing how the applicant will meet the relevant transparency requirements (in order to fulfil s251 support, GDPR and the DPA 2018), including (but not limited to) updating the Privacy Notice and engaging	Quorum of IGARD members	Quorum of IGARD members	N/A

			with relevant local women's health charities who may be representative of the cohort (in light of the fact that the applicant is not in contact with the cohort). The detailed plan will also include a timeframe for engaging with such charities and providing updated transparency information materials and incorporate the view of the women's health charity/ies of how to communicate with the cohort.			

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 Oversight and Assurance Report.

In addition, a number of applications were approved under class action (addition of Liaison Financial Service and Cloud storage):

- None notified to IGARD

Appendix B

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the Covid-19/COPI meeting held via videoconference

Tuesday, 5 May 2020

In attendance (IGARD Members): Kirsty Irvine (Chair), Imran Khan, Geoffrey Schrecker.

In attendance (NHS Digital): Vicky Byrnes-Watts, Liz Gaffney, Frances Hancox, Heather Pinches, Kimberley Watson, Vicki Williams.

1	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD BAU meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual DARS process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	NIC-372789-B6Q2B Public Health England (PHE) **Background:** The application is to assess the impact overall transmissions against the transmission of COVID-19 for people currently at a stated address. Presently there is no consistent data indicating household contact status within COVID-19 surveillance and monitoring datasets held by PHE in order to model scenarios. Existing NHS Digital datasets can be used to identify individuals with the same address and this linkable asset would enable PHE to undertake a range of analysis to support the pandemic response. NHS Digital noted that they were also continuing to discuss the application with NHS Digital's Caldicott Guardian and wider Information Governance (IG) directorate and that application would not be progressing via the usual DARS process but via the expediated IG route. **IGARD Observations:** IGARD members noted that this was an urgent and important piece of work and that there was real benefit in conducting this study in as near real time as possible, however, there was a parallel obligation to ensure that there was a mechanism to ensure that any possible interventions were delivered in as near real time as well. While the study was of potential great benefit, there were clear ethical issues to address in terms of proportionate intervention delivery. How would any interventions be implemented on an appropriate timescale to ensure that the intervention was carried out appropriately? How would the impact of the intervention be monitored and overseen? IGARD observed that the "intervention" may be as simple as providing timely advice direct to affected households or feeding into SAGE or other government advisory committees to be communicated more widely.

	IGARD members noted that on the face of the documents provided and datasets listed in the IG pro forma, it appeared to be personal data taking the form of a pseudonymised data set – however throughout the suite of draft documents the dataset was also referred to as "anonymised" and "confidential". IGARD suggested that this was reviewed, and a consistent description used throughout. IGARD members noted that there was a case that the dataset could be classed as pseudonymised and personal but not confidential data, but that a clear analysis should be undertaken to establish this fact especially because the additional datasets being added would create a particularly rich source of data. IGARD offered their ongoing support as the documentation is developed and updated. IGARD members noted that given the sensitivity and breadth of the data that it would not be suitable for PHE to onwardly share to third parties, as proposed in their supporting documentation, and suggested that the dataset be held by NHS Digital for any future access applications by third parties. NHS Digital has well established processes and procedures in place to support access to this dataset now and in the future. In addition - particularly because this data featured data from when COVID-19 data was first collected that it may not necessarily give the full picture provided by the wider testing that is now being carried out - there was a risk that onward sharing or those subsequently using this dataset may not appreciate the limitations inherent within the dataset. Accordingly, there was a risk that incorrect conclusions could be drawn from the data, particularly during the period of limited testing, and careful access controls could mitigate harmful inadvertent or wilful misinterpretation. NHS Digital noted that they would continue to work with the NHS Digital Caldicott Guardian and IG directorate to ensure a robust rationale and controls were in place. Noting next steps and that this application was still in the early stages, IGARD members would welcome this application coming to a future IGARD to support the review of updated supporting documentation and application. **Subsequent to the meeting:** IGARD queried whether a DPIA would be carried out for this dataset, in light of the processing of sensitive data on a large scale and NHS Digital confirmed that this was in-train.
2.2	<u>NIC-365354 -R3M0Q University of Oxford</u> **Background:** This was a verbal update to the application presented to the COVID-19 Response meeting on the 28th April 2020. This was an amendment application that had previously been approved by NHS Digital's SIRO on 31 March 2020 for access to data for the Randomised Evaluation of COVID-19 thERapY (RECOVERY). The study aims to compare several different treatments that may be useful for patients with COVID-19 and the new trial was classed as an 'Urgent Public Health Research Study'. NHS Digital noted that a number of additional supporting documents were available but had not been provided to the meeting for consideration. **IGARD Observations:** IGARD members were supportive of the additional datasets requested that were now available via NHS Digital and these were covered by the consent materials already reviewed, but that

	they would wish to review the new supporting documents relating to extending the cohort to under 18s. **Subsequent to the meeting:** The IGARD chair agreed to review the updated consent and protocol documents and provide any additional comments out of committee.
2.3	NIC-374190-D0N1M Genomics England **Background:** This was a verbal update to the application presented to the COVID-19 Response meeting on the 28th April 2020. The GenOMICC (Genetics of Susceptibility and Mortality in Critical Care) study aims to identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury. NHS Digital noted that the previous observations made by IGARD members had been discussed with the applicant and subsequent to that feedback, the applicant had updated their consent and study protocols and provided a data flow diagram to the DARS team. **IGARD Observations:** NHS Digital noted the applicant had stated that they could provide rapid feed back advice to the public on genomics, however IGARD members would welcome receiving the offered in-depth analysis giving an outline of the type of rapid response analysis they could provide that would produce genomic-related outputs within a few weeks to support intensive care management or assist in the management of the current pandemic. IGARD members noted that any additional datasets requested, in addition to those already requested, should ensure they have appropriate consent to address the Duty of Confidence and separately the quantum and type of data needed to be assessed under data protection legislation. It was suggested that when the applicant updates their application that a justification is made for each dataset requested and how each dataset will be used. In addition and noting that Primary Care data had been requested, IGARD members suggested that further clarity be provided for this particular dataset, since there were known issues with the data quality in this large wide-ranging dataset. IGARD members also suggested that any non-traditional datasets were discussed with the applicant to ensure appropriate and that no free text fields should be shared since they may contain confidential identifying information. Noting that this study was listed on the NIHR list of urgent national studies, IGARD members observed that it was potentially open to the applicant, as an interim measure, to proceed under COPI Regulation 3(3), if approved by NHS Digital's information governance (IG) directorate, and whilst the consent materials were revised and uplifted. However noting that revised consent materials were already in-train and the fact that this was a longer-term focussed study, it may be preferable for the applicant to continue proceeding via the consent route and not utilising COPI as this would avoid possible complications in future, for example study participants subsequently declining to give consent and having to be extricated from the study and/or exit issues when the legal basis under COPI expires.
2.4	NIC-190086-F5Z7B St Georges, University of London

	Background: The applicant wishes to expand the scope of their current Data Sharing Agreement (DSA) to get approval for additional COVID-19 related work which would involve changes to data specifications. Using HES-ONS linked data the applicant wishes to evaluate which persons from existing cohorts were diagnosed with COVID-19 and if any of these persons went on to die from cardiac or COVID-19 related disease. In addition to requesting COVID-19 related ICD and OPCS codes to existing filters, the applicant wish to received 2019/20 APC and CC (not outpatient or A&E). the information may give the applicant the opportunity to evaluate for COVID-19 risk factors which may be relevant to HEE and the medical community worldwide. NHS Digital had brought this application to the meeting for advice. **IGARD Observations:** IGARD members were supportive of the request, but that there should be a sound research question to answer and that the applicant should articulate the research question and consider whether the additional data they were requesting was sufficient, particularly in relation to those of the cohort that were tested as being 'positive' but not in hospital e.g. in the community or via a self-test for which they would not receive data. Thought should be given to the type of data requested and whether different types and/or additional data would support the applicant further. IGARD suggested that as per process, the application and full suite of supporting documents would need to be reviewed at Thursday IGARD meeting where recommendations could be made to see how the additional data requested fitted with the current approvals in place. If the applicant subsequently needed to extend their s251 support, for instance, IGARD members would facilitate this request via HRA CAG and support the applicant with the process.
2.5	<u>NIC-144568-D7G6V The Royal Brompton & Harefield NHS Foundation Trust</u> **Background:** This was an amendment application that was to be approved by the NHS Digital SIRO under precedent 1: Extensions and Renewals and had been previously reviewed by IGARD on the 30 August 2018. The DSA had expired in October 2019. Due to the current COVID-19 pandemic the Chief Investigator has requested quarterly data on HES-APC and mortality data for a 3 year period to enable specific monitoring of the short and long term risks from COVID-19 to individuals diagnosed with myocarditis. The focus on COVID-19 has been assessed by NHS Digital as being compatible with the approved purpose for processing the data under this Data Sharing Agreement (DSA) and the question of whether patients with a diagnosis of myocarditis face increased risks due to COVID-19 are within the scope. **IGARD Observations:** IGARD members had queried if the applicant would want to raise the upper age limit on their current data flows from the age of 80, given the age profile of patients hospitalised with COVID-19. NHS Digital confirmed that the applicant had not sought to increase the age range but they would discuss with the applicant if it would increase the benefits of the work outlined. IGARD members suggested that since the applicant was looking to obtain additional datasets and data years which could amount to over 6 million additional records, in addition to the 20 years of data they already held, that an assessment be made against NHS Digital's Data Minimisation Standard points and provided as a supporting document, along with updating the

	processing section of section 5 of the application providing a justification for the increased quantum of data requested. IGARD members also suggested that the applicant may wish to consider the limitation of the cohort to those with a myocarditis related diagnosis as the primary diagnosis and whether that could fulfil the research goal, since the guidance is that the COVID-19 related code should be listed as the primary diagnosis with any other condition codes listed as the other diagnosis. This would mean that any COVID-19 associated myocarditis patients will be absent from the cohort. NHS Digital suggested that they would discuss with the applicant and the NHS Digital production team to ensure these cohort members were not missed. IGARD members suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not receive additional data while work was undertaken to address the queries raised. IGARD suggested that as per usual process, the application and full suite of supporting documents would need to be reviewed at Thursday IGARD meeting where recommendations could be made to see how the additional data requested fitted with any revised processing activities within section 5 of the application.
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.