**Independent Group Advising on the Release of Data (IGARD)**

**Minutes of meeting held via videoconference 23 July 2020**

| **IGARD MEMBERS IN ATTENDANCE:** | |
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| **Name:** | **Position:** |
| Paul Affleck | Specialist Ethics Member |
| Maria Clark | Lay Member / IGARD Alternate Deputy Lay Chair |
| Prof. Nicola Fear | Specialist Academic Member |
| Dr. Imran Khan | Specialist GP Member |
| Dr. Geoffrey Schrecker | Specialist GP Member / IGARD Deputy Specialist GP Chair |
| **IGARD MEMBERS NOT IN ATTENDANCE:** | |
| **Name:** | **Position:** |
| Kirsty Irvine (Chair) | IGARD Lay Chair |
| Dr. Maurice Smith | Specialist GP Member |
| **NHS DIGITAL STAFF IN ATTENDANCE:** | |
| **Name:** | **Team:** |
| Garry Coleman | Data Access Request Service (DARS) |
| Dave Cronin | Data Access Request Service (DARS) |
| Catherine Day | Data Access Request Service (DARS) (Observer: item 2.1) |
| Duncan Easton | Data Access Request Service (DARS) (Observer: item 2.2) |
| Richard Hatton | Clinical Informatics (Observer: items 2.1 to 2.4) |
| Karen Myers | IGARD Secretariat |
| Bethan Thomas | Data Access Request Service (DARS) |
| Kimberley Watson | Data Access Request Service (DARS) |
| Vicki Williams | IGARD Secretariat |
| Tom Wright | Data Access Request Service (DARS) (Observer: item 2.2) |

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| **1** | **Declaration of interests:**<br>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. |

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| | Nicola Fear noted professional links to the team at University of Leeds (NIC-11809-H1Y3W) but noted no specific connections with the application and it was agreed that this was not a conflict of interest.<br><br>Paul Affleck noted professional links to University of Leeds (NIC-11809-H1Y3W) but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.<br><br>**Review of previous minutes and actions:**<br><br>The minutes of the 16th July 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.<br><br>**Out of committee recommendations:**<br><br>An out of committee report was received (see Appendix A). |
| **2** | **Data Applications** |
| **2.1** | <u>Health Data Research UK: R14.2 - CVD-COVID-UK. Cardiovascular disease and COVID-19: using UKwide linked routine healthcare data to address the impact of cardiovascular disease on COVID-19 and the impact of COVID-19 on cardiovascular diseases. (Presenter: Garry Coleman) NIC-381078-Y9C5K</u><br><br>**Application:** This was an amendment application to add 'COVID-19 Hospitalisation in England Surveillance System' (CHESS) and GPES Data for Pandemic Planning & Research (GDPPR) datasets, and to increase the number of Data Controllers.<br><br>The purpose is to establish a Cardiovascular Disease Trusted Research Environment (CVD TRE), to look at the effects of cardiovascular disease, and its risk factors and medications, on COVID-19 disease, also the direct and indirect impacts of COVID-19 on cardiovascular disease. The direct impacts include acute life-threatening complications, such as heart attacks, strokes and clots in the legs and lungs. In addition, since COVID-19 increases both inflammation and the risk of blood clots, there may be an increased risk of heart attack, stroke and other cardiovascular events in the medium and long term.<br><br>NHS Digital advised IGARD that the template had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 24th June 2020.<br><br>**Discussion:** IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 26th May, 2nd June, 9th June, 16th June and 23rd June 2020.<br><br>IGARD noted that this application had also been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (see Appendix B) on the 24th June 2020.<br><br>IGARD noted and endorsed the specific points raised by PAG. In particular, and in relation to the use of individual practitioner within the datasets requested, that PAG did not support the use of published analysis at individual practitioner level. IGARD specifically queried the ethical issues relating to this point and asked that a satisfactory exploration was provided of the ethical issues and how this would be managed. In addition, IGARD also advised that rather than publishing any such analyses, the applicant should consider liaising with a separate body, for example the Care Quality Commission.<br><br>IGARD queried the amendments requested in the application, in relation to adding the two additional datasets relating to GDPPR and CHESS data, and the request to increase the number of Data Controllers from four to six; and advised that it was not clear what the amendments were, and specifically who the new Data Controllers were; and asked that |

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| | section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to clearly outline these amendments.<br><br>IGARD noted the statement in section 1 *"Pseudonymised, record level data will be available to view but only summary, aggregated data will be able to download by the researchers."* and queried if this data was aggregated data, and were advised by NHS Digital that it was. IGARD noted the confirmation from NHS Digital and asked that section 1 and section 5 was updated with further information.<br><br>IGARD queried the NHS Digital location details that had been included in section 2(a) (Processing Locations) and section 2(b) (Storage Locations); and advised that NHS Digital had previously confirmed to IGARD that where NHS Digital were only providing access to the TRE, no location information was added to the application. IGARD therefore asked that the physical locations in section 2(a) and section 2(b) were removed to ensure consistency with other applications.<br><br>IGARD noted that section 3(a) (Data Access Already Given) had not been populated and were advised by NHS Digital that where an applicant has continuous access to the data in the TRE that it was continuously re-disseminated. IGARD noted, however that in terms of transparency, section 3(a) should be updated to accurately reflect that the data was currently being accessed and would be continuously disseminated.<br><br>In addition, IGARD also noted that previous iterations of the application reflected that SGSS data and Civil Registration Mortality were part of the DSA, however noted that these datasets were not included in section 3(b) (Additional Data Access Requested) of this application, and asked that this was updated to reflect these datasets.<br><br>IGARD noted reference in section 3(b) and section 5(b) (Processing Activities) reference to '*future cardiovascular conditions*' and asked that a further explanation of this was provided, for example would the HES data requested provide any information on any of those specific cardiovascular conditions.<br><br>IGARD queried the data minimisation that had been applied, specifically in light of the purpose of the application, which was to look at the effects of cardiovascular disease, and its risk factors and medications, on COVID-19 disease; andqueried why data from 1989 had been requested and how this would benefit the COVID-19 purpose. IGARD asked that the application was updated to be explicitly clear that for those patients who died prior to COVID-19, their data would not be included within the data disseminated, since it served no purpose, and that was in line with NHS Digital's Data Minimisation Standard 3.<br><br>In addition, IGARD noted the references in section 1 and section 5(b) to "interim" data minimisation measures, and queried who would oversee these measures after the interim period had passed, and discussed the role of the CVD-COVID-UK Oversight Committee that was set-up by the applicant, in particular noting its Terms of Reference (ToR); and asked that these ToR were updated to clarify that data minimisation was part of the remit of the oversight committee.<br><br>IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD queried the transparency of the work outlined in the application and the available information on the HDR UK website, and asked that a special condition was inserted in section 6 (Special Conditions), that for transparency, and linked to the privacy notice, further study details, including analysis plans, protocols and reports, would be shared on the HDR UK website, and within 2 months of signing the Data Sharing Agreement (DSA). |

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| | IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route.<br><br>**Outcome:** recommendation to approve subject to the following condition:<br><br>1. To provide a satisfactory exploration of the ethical issues related to the publication of practitioner level data and how this will be managed.<br><br>The following amendments were requested:<br><br>1. To update section 1 and section 5 with narrative in respect of the GDPPR data and the two new Data Controllers.<br>2. To update section 1 and section 5 with further information on the aggregated data.<br>3. To remove reference in section 2(a) and 2(b) to the physical location, to be consistent with similar applications.<br>4. To update section 3(a) to be clear that data is currently being accessed and will be continuously disseminated.<br>5. To update section 3(b) to add SGSS and Mortality data, as per previous iterations of the application.<br>6. To include in section 5(b), reference and explanation to 'future cardiac conditions' as per previous iterations of the application.<br>7. To be clear that for those who died prior to COVID-19, their data will not be included within the data disseminated, since it serves no purpose (NHS Digital's Data Minimisation Standard 3).<br>8. To include a special condition in section 6, that for transparency, and linking to the privacy notice, further study details (including analysis plans, protocols and reports) will be shared on the HDR UK website, and within 2 months of signing the DSA.<br>9. To update the ToR with clarification that data minimisation is part of the remit of the oversight committee.<br><br>The following advice was given:<br><br>1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment.<br>2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.<br><br>It was agreed the condition would be approved OOC by IGARD members.<br><br>**Subsequent to the meeting**<br><br>It was noted that before IGARD's last review of this application on the 25th June 2020, it did not receive the PAG feedback from their meeting on the 24th June. Therefore, IGARD were not previously able to provide a review based on any information / points from the PAG review. |
| **2.2** | <u>NHS England (SKH): GDPPR COVID-19 – NHS England - Pseudo (Presenter: Garry Coleman) NIC-384608-C9B4L</u><br><br>**Application:** This was a new application for GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR) data. COVID-19 has led to a change in demand on general practices, including an increasing number of requests to provide patient data to inform planning and support vital insights on the cause, effects, treatments and outcomes for patients of the virus. To support the response to the COVID-19 outbreak, NHS Digital has been legally directed to collect and analyse healthcare information about patients, including from their GP record, for the duration of the COVID-19 emergency period, under the COVID-19 Public Health Directions 2020 (COVID-19 Direction). All GP practices in England are legally required to share data with |

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| | NHS Digital for this purpose under the Health and Social Care Act 2012. This collection will reduce burden on general practices, allowing them to focus on patient care and support the COVID-19 response.<br><br>**Discussion:** IGARD noted that this application had also been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (see Appendix B) on the 22nd July 2020. IGARD noted and endorsed the specific points raised by PAG and noted the queries raised for IGARD's consideration.<br><br>In relation to the first query raised by PAG, that *"IGARD satisfied themselves that public and professional trust does not become undermined through any GP data sharing with such companies"*; IGARD discussed and, in light of the volume of data requested, suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / Data Sharing Agreement (DSA).<br><br>In relation to the second query raised, that *"IGARD consider whether a Trusted Research Environment (TRE) could satisfy some of NHS England's requirements…"*, IGARD asked that NHS Digital provided confirmation whether or not the applicant could access the NHS Digital data in an NHS Digital TRE; and if they could not, that a further explanation was provided as to why not.<br><br>IGARD also supported and echoed the point raised by PAG, that any requests for further dissemination of the data, must go through the existing DARS/PAG/IGARD process; and asked that a special condition was inserted in section 6 (Special conditions) that any further dissemination of the GDPPR data under this DSA should be subject to oversight from a group represented by the GP profession and patients/Lay members.<br><br>IGARD also suggested If there were any substantial amendments to the application, these should go via PAG prior to being reviewed by IGARD.<br><br>In addition to the points raised by PAG, IGARD also asked that section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) were updated to provide clear justification for that data requested and any onward dissemination of the data.<br><br>IGARD queried how the provision of the specific GDPPR data requested would meet the objectives, noting that the explanation provided in section 5(a) lacked clarity, and asked that further clarification was provided.<br><br>In addition, IGARD also noted that the information within the application in terms of the linkage of data seemed to be contradictory, and asked that clarification was provided within the application as to whether the GDPPR data would be linked, with a further explanation of the purpose for this, and to provide details of the process of any linkage.<br><br>IGARD noted in section 3(c) (Patient Objections) that *"Type 1 Objections have already been applied at a GP practice level prior to the GPES collection by NHS Digital"* and that "*National Opt-outs are not applied for pseudonymised data released for the purpose of COVID-19";* and asked that section 3 (Datasets Held / Requested) was updated to address the Common Law Duty of Confidentiality, with the application of National Data Opt Out, in regards to the use of a statutory exemption versus the nature of the data as pseudonymised data and to make this consistent.<br><br>IGARD noted the information provided in section 5(a) that outlined how the data may be used, and asked that the introduction to this information was amended to accurately state *"…cases of the data include **and** are limited to the *COPI Regulations"* (*The Health Service (Control of Patient Information) Regulations 2002).<br><br>*IGARD also noted the reference within this list to "*Patient stratification and predictive modelling", and asked that section 5(a) was updated with further clarification, that clearly |

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| | distinguished between Risk Stratification for the purpose of modelling and planning, and the purpose of identification of individuals for individual intervention, for example the COVID-19 patient shielding list.<br><br>IGARD noted in section 7 (Ethics Approval) that Ethics approval was not required due to the data not being for the purpose of research, however asked for further clarity on the use of COPI Regulations for the use of pseudonymised data and suggested that the applicant consider whether REC approval should be sought.<br><br>IGARD noted that whilst section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) did provide further information of the specific outputs and benefits expected, there were no details of the target dates for these outputs; and suggested that the applicant update these sections to provide further information of the target dates for this urgent dissemination of data.<br><br>IGARD noted and discussed the applicant's proposals in terms of sub-licensing, in particular, whether this was the appropriate for this application, or whether other options could be explored, for example, adding additional joint Data Controller(s) and / or Data Processor(s); or whether other organisations should apply directly to NHS Digital for access to the data; and asked that further justification of the sub-licensing was provided.<br><br>IGARD also discussed if any commercial organisations were involved in the sub-licensing, and asked that confirmation was provided; and if they were, confirmation was provided that the application would come through NHS Digital for an amendment, as per process.<br><br>In addition, IGARD asked for confirmation that if a sub-licensing model were used, NHS Digital would maintain a public and transparent register of all such sub-licenses together with details of data disseminated.<br><br>IGARD noted the large number of processing and storage locations listed in section 2 (Locations), and advised that any additional locations, would constitute an amendment, and suggested that this would not be suitable for NHS Digital's Precedent route or Director / IAO approval.<br><br>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 update their privacy notice to reflect the new dataset requested; and to ensure that this was compliant with NHS Digital's Data Minimisation Standard 3.<br><br>IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route.<br><br>**Outcome:** Recommendation to defer, pending:<br><br>1. IGARD endorsed the comments made by PAG and in reference to the two specific requests from PAG, suggested that<br>a) NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement.<br>b) NHS Digital to provide confirmation whether or not the applicant could access the NHS Digital data in an NHS Digital TRE; and if not, why not.<br>2. To update section 3 to address the Common Law duty of Confidentiality, with the application of National Data Opt Out, in regards to the use of a statutory exemption versus the nature of the data as pseudonymised data and to make this consistent.<br>3. IGARD suggested that NHS England update their privacy notice to reflect this new dataset and to ensure compliance with the NHS Digital Standard.<br>4. To update section 5(a) and section 5(b) to provide justification for the data requested, and any onward dissemination of the data. |

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| | 5. To amend section 5(a) to state *"…cases of the data include **and** are limited to the COPI Regulations"*<br>6. To provide further clarification in section 5(a) of how the provision of the GDPPR data will meet the objectives.<br>7. To clarify within the application as to whether the GDPPR data will be linked, explain the purpose for this and provide details of the process of linkage.<br>8. To provide clarification in section 5(a), clearly distinguishing between Risk Stratification for the purpose of modelling and planning, and the purpose of identification of individuals for individual intervention.<br>9. IGARD suggested that the applicant provide further information in section 5(c) and section 5(d) of the target dates for this urgent dissemination of data.<br>10. To insert a special condition in section 6 that any further dissemination of the GDPPR data under this DSA should be subject to oversight from a group represented by the GP profession and patients/Lay members.<br>11. To provide further clarity on the use of COPI Regulations for the use of pseudonymised data and to consider whether REC approval should be sought.<br>12. To provide justification as to whether sub-licensing is the appropriate route for this application or whether other options, including (but not limited to) adding as joint Data Controller(s) and / or Data Processor(s); or other organisations applying directly to NHS Digital.<br>13. To confirm if any commercial organisations are involved in sub-licensing and if so, confirmation that the application will come through NHS Digital for an amendment.<br>14. To confirm that if a sub-licensing model is used, NHS Digital will maintain a public and transparent register of all such sub-licenses together with details of data disseminated.<br>15. IGARD suggested If there are any substantial amendments to this application, this should go via PAG prior to being reviewed by IGARD.<br>16. Accepting the large number of processing and storage locations listed, any additional locations, would constitute an amendment, and as such would not be suitable for NHS Digital's Precedent route or Director / IAO approval.<br>17. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment.<br>18. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. |
| **2.3** | <u>PDS Class Action Application: An amendment for Clinical Commissioning Groups (CCGs) to receive: Personal Demographics Service (PDS) data (Presenter: Stuart Gunson) NIC-383553-S6Z8M</u><br><br>**Application:** This was a new Class Action application for all CCGs in England to receive the underlying record-level data for the Personal Demographics Service (PDS). The main purpose of the PDS is to support direct care, although data extracted from PDS may also be supplied for secondary uses. Pseudo PDS for the purpose of Commissioning will: support measuring the health, mortality or care needs of the total local population; support protecting or improving the public health of the total local patient population; enable the CCG to be able to see early indications of potential practice resilience issues in that an early warning marker can often be a trend of patients re-registering themselves at a neighbouring practice. Identifiable PDS for the purpose of invoice validation will: support validating financial payments for contracted and non-contracted activity, determining if the CCG is the responsible commissioner for the patient.<br><br>NHS Digital advised IGARD that there was an error within the application that stated identifiable data would only be used for direct care, and advised that this would need |

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| | amending to reflect that identifiable data would be used for Invoice Validation only, and to remove any reference to "direct care".<br><br>**Discussion:** IGARD noted and supported the update from NHS Digital in respect of the application being updated to reflect that identifiable data would be used for Invoice Validation only, and for reference(s) to "direct care" being removed.<br><br>IGARD noted that the finalised briefing paper provided as a supporting document stated the data retention period was 20-years and asked that the application was updated to provide further clarity of the discrepancy in text, for example, does the retention period begin when the data is disseminated.<br><br>IGARD noted the benefits outlined, however queried why there were no details of the target dates for these benefits; and asked that the applicant update the relevant section to provide further information of the target dates.<br><br>IGARD queried if National Data Opt Outs are applied for the flow of data outlined in the application, and asked that further justification was provided throughout the application as to whether the National Data Opt Out does or does not apply, and that further justification of this was provided.<br><br>IGARD noted a number of acronyms were noted in section 5 (Purpose / Methods / Outputs) and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader.<br><br>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 CCG's updated their privacy notices to reflect the new dataset; and to ensure that this was compliant with NHS Digital's Data Minimisation Standard 3.<br><br>**Outcome:** recommendation to approve<br><br>The following amendments were requested:<br><br>1. To update the application to clarify the data retention period.<br>2. To remove reference(s) to *"direct care"*.<br>3. To update the Benefits section to ensure the target dates are included.<br>4. To provide justification throughout the application as to whether the National Data Opt Out does or does not apply, and the justification for this.<br>5. To amend section 5 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.<br><br>The following advice was given:<br><br>1. IGARD suggested that the CCGs update their privacy notices to reflect this new dataset and ensure compliance with NHS Digital's Standard. |
| **2.4** | <u>University of Nottingham: Evaluating protocols for identifying and managing patients with FH (Presenter: Kimberley Watson) NIC-300282-G9Q0Q</u><br><br>**Application:** This was an amendment application to 1) merge existing Data Sharing Agreements, NIC-300282-G9Q0Q and NIC-115405-P6X6Q-v0.11 as both DSAs are for the same purpose; 2) to remove UCL as a Data Controller; 3) to add the University of Nottingham and University of York as Data Controllers who also process data; 4) to add previously disseminated HES datasets under NIC-115405-P6X6Q to section 3a as data held; 5) to include the new Cohort Management and automated extract service products to replace future |

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| | dissemination of the previously approved Medical Research Information Service (MRIS) products.<br><br>The purpose is for a study to evaluate protocols for identifying and managing patients with Familial Hypercholesterolaemia (FH), an inherited condition that means their cholesterol levels are higher than normal from birth. The study team propose in this programme of research to evaluate treatment patterns and short- and long-term cardiovascular outcomes and the NHS costs of patients with FH. The outputs of this linkage request will result in providing the most accurate and up-to-date outcome of FH patients to date.<br><br>**Discussion:** IGARD noted that following the last review of this application on the 15th November 2018 when the application was recommended for approval, IGARD had specifically queried the correct cohort numbers in light of the conflicting information in the application and the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support and asked for an amendment to be made. IGARD noted that this had still not been addressed and again asked that the cohort numbers quoted in the application were cross referenced with the HRA CAG supporting documents provided and ensure they are correctly aligned.<br><br>In addition, IGARD also queried if the application related only to the s251 cohort, or if there was also a consented cohort, due to the discrepancy between the application and supporting documents; for example supporting document 8.2, the 2015 HRA CAG application, that stated "…*all newly registered patients would prospectively give written consent for flagging by the NHS central register*…"; and asked that confirmation was provided.<br><br>IGARD queried the statement in section 1 (Abstract) that "*NHS Digital already hold the study cohort so UCL do not need to submit cohort patient identifiers under this agreement*", and asked that clarification was provided in section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) as to whether NHS Digital already holds the cohort data, or if UCL will be flowing the identifiable data into NHS Digital, since it was unclear.<br><br>IGARD noted that supporting document 3.1, the 2019 HRA CAG amendment form submitted as part of the annual review process, did not reflect any changes to the Data Controllership arrangements for this application, and asked that written confirmation was provided that HRA CAG had been notified of this change and were satisfied, before any NHS Digital data flowed.<br><br>IGARD noted a number of Principal Investigators in supporting document 1.0, the study protocol, and queried whether they should also be considered as joint Data Controllers, and asked that further confirmation of this was provided in section 1 and section 5 (Purpose / Methods / Outputs); and that if they were also considered joint Data Controllers, that the application was update accordingly to reflect this.<br><br>IGARD noted the reference in section 5(b) to the territory of use was the "UK" and asked for further clarity on this, in light of information in the protocol that stated that Principal Investigators were based in Scotland, and noting that section 2(c) (Territory of Use) stated the territory of use was *"England and Wales"*.<br><br>IGARD queried conflicting information in section 5(a) that stated NHS Digital would provide the data to the approved recipient at each University; and section 5(b) that stated the University of Nottingham would securely share the data with University of York. Since the data flowing from NHS Digital was unclear, IGARD asked that both sections were updated to clarify the flow of NHS Digital data to the University of Nottingham and / or the University of York.<br><br>IGARD queried if any yielded benefits had been generated, noting that that this was a long running study, and asked that further examples of measurable and yielded benefits were provided in section 5(d) (Benefits) (iii) (Yielded Benefits) with a clear timescale for outputs, for transparency. |

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| | IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, IGARD suggested that it be updated to comply with the General Data Protection Regulation (GDPR), and to meet NHS Digital's Standard.<br><br>**Outcome:** Recommendation to defer, pending:<br><br>1. To cross reference the cohort numbers in the application and the supporting document's and ensure they are aligned.<br>2. To provide clarification in section 5(a) and section 5(b) as to whether NHS Digital already holds the cohort data, or if UCL will be flowing the identifiable data into NHS Digital.<br>3. To provide written confirmation that HRA CAG have been notified of the change in Data Controllership.<br>4. To provide confirmation in section 1 and section 5 as to whether the various Principal Investigator organisations should also be considered as joint Data Controllers, and if so, to update the application accordingly.<br>5. To confirm whether the application relates only to the s251 cohort or if there is also a consented cohort, due to the discrepancy between the application and supporting documents.<br>6. To update section 5(a) and section 5(b) to clarify the flow of NHS Digital data to the University of Nottingham and / or the University of York.<br>7. To clarify the reference in section 5(b) to the "UK" territory of use.<br>8. To provide more examples of measurable and yielded benefits within section 5(d) (iii) of the application and with a clear timescale for outputs.<br>9. To update section 4 to ensure the privacy notice is GDPR compliant and meets NHS Digital's Standard. |
| **2.5** | <u>University of Leeds: Yorkshire Specialist Register of Cancer in Children and Young People (Presenter: Dave Cronin) NIC-11809-H1Y3W</u><br><br>**Application:** This was an extension, amendment and renewal application which had come for advice for identifiable Hospital Episode Statistics (HES), Mental Health and Learning Disabilities Data Set (MHLDDS), Mental Health Minimum Data Set (MHMDS) and Mental Health Services Data Set (MHSDS). It was also an amendment application to: 1) allow data linkage with the Department for Education (DfE), in order to link to education records; 2) to link to Public Health England (PHE) data; 3) to include the linkage of all data sources, including primary and secondary care information, from the various data providers to create an individual-level patient record for each patient within the registry; 4) to follow-up patients diagnosed with secondary malignant neoplasms (SMN); 5) the addition of the 2 PhD's. In addition, NHS Digital were also seeking advice from IGARD in relation to linkage with the Department of Work and Pensions (DWP) data, for the purpose of seeing whether patients in the patient cohort are in receipt of various benefits and to investigate their employment history, for the purposes of social welfare research.<br><br>The YSRCCYP is a regional population-based register containing detailed demographic and clinical information on children and young adults aged 0-29 years diagnosed with cancer since 1974, with the purpose of facilitating population-based epidemiological and health services research. The YSRCCYP research team's research plans include the following objectives: 1) to describe the total workload of hospitalisation among the Yorkshire cancer population aged 0-29 years, to identify clinical and sociodemographic factors which influence the likelihood of hospitalisation and to investigate how hospitalisation rates have changed since 1997; 2) to understand patient care pathways through the NHS before, during and after cancer diagnosis. This includes assessment of time to diagnosis for children and young adults diagnosed with |

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| | cancer under the age of 30 years to identify where improvements can be made to minimise delays in diagnosis leading to better prognosis and less stress and anxiety on patients and their families; 3) to calculate the risks and costs to the NHS of adverse health events requiring hospital admission for survivors of cancer in this age group so that clinicians can provide appropriate follow-up care.<br><br>**Discussion:** IGARD noted the importance of the research; and welcomed the application which had come for advice and without prejudice to any additional issues that may arise when the application was fully reviewed.<br><br>IGARD noted in section 1 (Abstract) that advice had been sought on the legal basis for linkage from colleagues in NHS Digital's Information Governance, who had advised that *"there may be a sufficient legal basis"*, and asked that confirmation was provided that the legal basis was sufficient as per NHS Digital's Legal Basis Standard.<br><br>IGARD noted the request for the HES Accident and Emergency (A&E) data and queried if this was correct, noting that this data was no longer being produced by NHS Digital; and asked that section 3(b) (Additional Data Access Requested) was updated to clarify HES A&E was the correct dataset required, or if data from the Emergency Care Data Set (ECDS) was required. If ECDS was required, to provide clarity if it would replace or run alongside HES A&E for a short time period.<br><br>IGARD noted in section 1 and section 5(b) (Processing Activities) that the applicant was wanting to obtain information on employment history and income details from DWP, and advised that this information would not be available via the DWP data, and would only be available via HM Revenue and Customs (HMRC).<br><br>IGARD noted that there was an overlap with the s251 support and consent, and that the Health Research Authority Confidentiality Advisory Group's (HRA CAG) letter of support from the 20th September 2019, specifically stated that the transparency materials would need updating within 6-months. IGARD advised NHS Digital that the revised transparency materials provided for review did not appear to have met the HRA CAG conditions of support, and therefore asked that written evidence was provided from HRA CAG that they were content with the revised materials and support continued.<br><br>IGARD also noted that the Patient Information Sheet (PIS) and the Research Ethics Committee (REC) approval documentation that had been provided for review, did not match the published documentation on the study website, or those approved by HRA CAG, and asked that copies of all current documentation were provided; and uploaded to NHS Digital's Customer Relationship Management (CRM) system for any future review.<br><br>IGARD noted that there was inconsistent information throughout the application in respect of the cohort numbers, and that these figures did not match information within the supporting documents, and asked that the application was updated to ensure the correct cohort numbers were referenced and to ensure consistency with the supporting documents provided.<br><br>IGARD queried the information provided in section 5(a) (Objective for Processing) in respect of the purpose for processing the data, and asked that this was updated to ensure it met NHS Digital's Objective for Processing Standard 5a.<br><br>IGARD queried the information in section 5(a) in respect of the proposed data linkage, for example the references to linking with primary care data; and asked that this was updated with further information on the data linkage and how this linkage to primary care data would take place. |

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| | IGARD also queried if the Data Controllers for the external dataset had approved the linkage, noting that NHS Digital could not give that permission, and asked that this was clarified in section 5(a).<br><br>IGARD noted the outputs listed in section 5(c) (Specific Outputs Expected) and queried whether these were in the past, and asked that these were updated to also reflect the current and any future target dates. IGARD also asked that section 5(d) (Benefits) was updated with further information of the yielded benefits accrued to date and ensure these were clear as to the benefits to both patients, and the health care system more generally.<br><br>In addition, IGARD also queried how the outputs and benefits outlined to the Health and Social Care System in England and Wales would be established, and the further details of the benefits flowing to patients; and asked that section 5(c) and section 5(d) were updated to clarify this.<br><br>IGARD queried the references within the application to the PhD students having honorary contracts with the University of Leeds, and suggested that this was removed as this was not the usual process / approach that Universities take for PhD students.<br><br>IGARD suggested that the applicant may wish to consider speaking to colleagues across the academic field, specifically with regards to the National Data Opt Out and how participants can withdraw from Registries, such as the Teenage Cancer Trust or others.<br><br>IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that applicant's privacy materials were updated to ensure they were General Data Protection Regulation (GDPR) compliant and met NHS Digital's standard, including (but not limited to) referencing National Data Opt Outs, how a participant could withdraw from the study, and that this was written in a language suitable for the age range and lay reader.<br><br>IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, and in light of this it was suggested that NHS Digital might wish to consider a short term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.<br><br>**Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.<br><br>1. Noting the NHS Digital IG advice that the legal basis 'may be sufficient', to provide confirmation that the legal basis **is** sufficient as per DARS Legal Basis Standard.<br>2. To clarify in section 3(b) if HES A&E is the correct dataset required, and if ECDS data is required, if it will replace or run alongside HES A&E for a short time period.<br>3. To update the privacy materials to ensure they are GDPR compliant and meeting DARS standard, including (but not limited to) referencing National Data Opt Outs, how a participant can withdraw from the study, and that this is written in a language suitable for the age range and lay reader.<br>4. To provide written evidence from HRA CAG that they are content, noting their condition of approval, that transparency material have been updated and within the 6-month timeframe outlined by HRA CAG.<br>5. To provide copies of all current PIS and REC approval documentation, as the documentation provided for review did not match the published documentation on the study website or those approved by HRA CAG. |

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| | 6. To update the application throughout to ensure the correct cohort numbers are referenced and to ensure consistency with the supporting documents provided.<br>7. To update section 5(a) to ensure it meets NHS Digital's Purpose Standard.<br>8. To provide further information in section 5(a) on the data linkage and how this linkage to primary care data will take place.<br>9. To clarify in section 5(a) that in respect of linking to any external dataset, that the Data Controller for those datasets has approved the linkage, since it is not for NHS Digital to give that permission.<br>10. To update section 5(c) to reflect the current and future targets dates.<br>11. To update section 5(c) and section 5(d) to clarify how the outputs and benefits outlined to the Health and Social Care System in England and Wales will be established; and further details of the benefits flowing to patients.<br>12. To remove reference to PhD students having honorary contracts since this is not the usual approach.<br>13. To provide written evidence of the most recent REC approval and ensure that this is uploaded to NHS Digital's CRM system.<br>14. To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally.<br>The following advice was given:<br>1. IGARD suggested that the applicant may wish to consider speaking to colleagues across the field, with regard to the National Data Opt Out and withdrawing from the Registries, such as the Teenage Cancer Trust or others.<br>2. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, and in light of this it was suggested that NHS Digital might wish to consider a short term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.<br>3. IGARD advised that the employment history and income details that the applicant wishes to access, is not available via DWP, and that this is only available via HMRC. |
| **2.6** | University of Liverpool: MR1025 – The Roy Castle Lung Cancer Research Programme, Liverpool Lung Project – University of Liverpool (Presenter: Dave Cronin) NIC-147982-J7KGV<br>**Application:** This was renewal application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES), Civil Registration, Cancer Registration Data and Demographics data; and an amendment to include the new Cohort Management and automated extract service products to replace future disseminations of the previously approved MRIS products.<br>The purpose is for a longitudinal observational study aimed at identification of risk factors and biomarkers that will allow improved early detection and treatment of lung cancer and respiratory disease. The aims are to: determine factors associated with the risk of lung cancer (to help identify ways to select people for screening); identify better ways to detect lung cancer earlier (to improve diagnosis, which will save lives); to better understand the biology of lung cancer (leading to potential new therapies); identify ways of selecting patients for the best current and future treatment; contribute to improving patients' outcome and ultimately save lives. |

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| | NHS Digital advised IGARD that new versions of the protocol, Research Ethics Committee (REC) approval and the Patient Information Sheet and consent forms had been submitted to IGARD as part of the review, however this had not been made clear within the application and that section 1 (Abstract) would be updated to reflect this.<br><br>NHS Digital also advised that the cohort number stated in section 1 were incorrect and did not align with other parts of the application and the latest REC approval and would need updating.<br><br>**Discussion:** IGARD noted and supported the update from NHS Digital in respect of the update to section 1 to reflect the latest documentation. IGARD also noted the update in respect of the incorrect cohort number and asked that section 1 and section 5(a) (Objective for Processing) were updated to confirm the correct cohort numbers and to ensure that this was aligned with the latest REC approval.<br><br>IGARD noted that section 5(e) (Is the Purpose of this Application in anyway Commercial) that the application was not considered to be commercial, however discussed if anyone receiving the NHS Digital in a derived format could be classed as commercial; and asked that section 5(e) was revised to ensure compliance with NHS Digital's Commercial Purpose Standard 5(e).<br><br>IGARD noted that the that the applicant did meet NHS Digital's Standard for privacy notices, however queried information provided in supporting document 15, the privacy notice checklist that still showed outstanding issues, and asked that the applicant's privacy notice was re-checked and clarification was provided in section 1 and section 4 (Privacy Notice) confirming if this had or had not been met.<br><br>IGARD noted the information provided in section 5(d) (Benefits) in relation to the benefits flowing, however asked that was updated with further information of the yielded benefits accrued to date and to ensure these were clear as to the benefits to both patients, and the health care system more generally. IGARD also suggested that the applicant provide further information in section 5(d) of the target date of the expected measurable benefits to Health and/or Social Care.<br><br>IGARD queried the transparency arrangements for the sharing of the NHS Digital data, and asked that a special condition was inserted in section 6 (Special Conditions) that the applicant would publish a list of data that had been shared; and in addition, provide NHS Digital with a list of the organisations who the derived data had been shared with, and ensure that this was publicly available.<br><br>IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route.<br><br>IGARD suggested that due to some of the issues that had been raised, the term of the Data Sharing Agreement (DSA) was adjusted to 1 year from the signing of the agreement.<br><br>**Outcome:** recommendation to approve for 1 year.<br><br>The following amendments were requested:<br><br>1. To revise section 5(e) to ensure compliance with NHS Digital's Commercial Purpose Standard 5(e).<br>2. To prove clarification in section 1 and section 4 as to whether the applicant's privacy notice has or has not been met the requirements.<br>3. To update section 5(d) to clarify how the outputs and benefits outlined to the Health and Social Care System in England and Wales will be established; and further details of the benefits flowing to patients. |

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| | 4. To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally.<br>5. To update section 1 and section 5(a) to confirm the correct cohort numbers and ensure that this is aligned with the latest REC approval.<br>6. To insert a special condition in section 6 that the applicant will:<br>a) Publish a list of what data has been shared.<br>b) Provide NHS Digital with a list of the organisations who the derived data has been shared with, and ensure that this is publicly available.<br><br>The following advice was given:<br><br>1. IGARD suggested that the term of the Data Sharing Agreement was adjusted to 1 year from the signing of the agreement.<br>2. IGARD suggested that the applicant provide further information in section 5(d) of the target date of the expected measurable benefits to Health and/or Social Care.<br>3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment.<br>4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. |
| **3** | <u>Returning Applications</u><br><br>Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role. |
| **4** | <u>COVID-19 update</u><br><br>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 The Health Service Control of Patient Information (COPI) Regulations 2002 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.<br><br>The ratified action notes from Tuesday 21st July can be found attached to these minutes as Appendix C.<br><br>IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting. |
| **5**<br><br>**5.1** | <u>AOB:</u><br><br><u>DARS - Covid-19 Response - Extension and Renewal Proposal</u><br><br>In advance of the meeting, a copy of the draft COVID-19 Response – Extension and Renewal Proposal document was circulated to members for any comments. IGARD confirmed that in light of the current climate, they were supportive of the processes outlined within the document.<br><br>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. |

## Appendix A

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 17/07/20

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) |
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| NIC-359692-Q4X1C | Lightfoot Solutions UK Ltd | 21/05/2020 | 1. To provide a satisfactory explanation of the operation of the Lightfoot HES Group, including Terms of Reference or guiding principles, composition of the group and other internal arrangements, for example minutes etc.<br>2. To provide justification of why data is being accumulated and not deleted on a rolling basis; and an explicit rationale of why historical aged data is being retained. | IGARD members | Quorum of IGARD members | N/A |
| NIC-349486-Y3C3L | Market and Opinion Research International Limited | 07/05/2020 | 1. To provide further details of:<br>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.<br>b) How those “under-represented” groups are being engaged with either now or in the future.<br>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. | IGARD members | Quorum of IGARD members | N/A |

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| | | | 2. In respect of the three groups outlined (those responding, non-responders and those eligible for the survey), to confirm;<br>a) what data is being held for each group and where the data comes from.<br>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. | | | |
| NIC-381078-Y9C5K | Health Data Research UK | 25/06/2020 | 1. In respect of the TRE:<br>a) To set up an independent oversight body.<br>b) To produce a detailed Terms of Reference document which addresses:<br>i. The process for approving projects.<br>ii. Who is responsible for the various activities carried out in the TRE.<br>iii. How the data controllers will work together and share responsibilities (to satisfy Article 26 of GDPR)<br>iv. Suitable checks and balances (for instance the composition of the oversight body).<br>v. How transparent minutes and records will be kept for the oversight body business.<br>c) The independent oversight body furnishes NHS Digital with a report on a quarterly basis, detailing the projects undertaken. | IGARD members | The IGARD Chair, under Chair's authority and due process as outlined in IGARD's Terms of Reference | The following comments were made with reference to condition 1c:<br>• More than one independent lay member to ensure consistent coverage and representation<br>• ToR should refer to the documents that define the "scope of the programme of work" and the contract with NHS Digital.<br>• How the data controllers work together should be set out in more detail in the ToR and could be in the privacy notice (see Article 26(2) GDPR). |

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**

## GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 24th June 2020

| **Application: DARS-NIC-381078-Y9C5K (v0.10)**<br>**Organisation name: University of Leicester**<br>**Profession Advisory Group Agenda item: 1** |
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| The group recognised the benefit and approach of the Trusted Research Environment, and the due diligence that would be applied to individual projects to ensure that data is appropriately minimised.<br><br>As a principle, PAG would request all research using GP Data to be published openly irrespective of its findings. This enhances the safety and progress of clinical research and maintains patient safety.<br><br>PAG encourage the auditing of use within the TRE and support the work of the audit team in moving to audit use of TRE instead of physical audits as more use occurs of the TRE. PAG advise that researcher access is via a two-factor authentication.<br><br>PAG note the use of individual practitioner within the datasets requested, but do not support the use of published analysis at individual practitioner level.<br><br>PAG note and support the excellent work being undertaken in relation to public and patient engagement. |

| Attendees | Role | Organisation |
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| Arjun Dhillon | Chair, Caldicott Guardian | NHS Digital |
| Garry Coleman | Associate Director of Data Access | NHS Digital |
| Anu Rao | GPC IT Policy Lead | BMA |
| Amir Mehrkar | GP, Clinical Researcher | RCGP |
| Julian Costello | GP | RCGP |
| Pam Soorma | Secretariat | NHS Digital |
| Helen Buckels | Secretariat | NHS Digital |

## GPES Data for Pandemic Planning and Research - Profession Advisory Group

## Record of feedback: Wednesday, 22nd July 2020

**Application: DARS-NIC-384608-C9B4L-v0.2**

**Organisation name: NHS England**

**Profession Advisory Group Agenda item: 2**

*A Conflict of Interest was declared by Amir who has a interest in NHS England's OpenSafely C19 Research Platform, which is another data set of significant GP Data under NHS England's data controllership. In view of this, Amir was in observer status and nominated Marcus Baw (HIG RCGP chair) to inform the discussions. The Chair has agreed for Marcus Baw to join PAG to represent RCGP in addition to Amir's (observer) attendance.*

PAG members do not currently support this application in its current form. However, PAG noted its importance and significance: NHS England, as the national commissioning organisation, plays a key role in using data to improve patient outcomes in relation to the pandemic. PAG is keen to support NHS England, mindful of the following issues:

- PAG noted the need to ensure a balance in relation to the volume and disclosive nature of the data, and risks and benefits to the sharing of such data. The request lacked sufficient detail of clear use cases and was therefore deemed an excessive request for all of the GP Data GPES extract.
- There seemed to be a blurring between secondary uses of data for commissioning and planning purposes as well as direct care (e.g. screening, monitoring, locating and risk stratification). PAG supports NHS England's role for commissioning purposes only.
- There were substantive concerns raised around the fact that NHSE would be able to share and further disseminate the data; this is what was implied by the application. Any such request for further dissemination must go through the existing DARS/PAG/IGARD process; anything else would undermine that prior agreement with the BMA/RCGP and trust gained with the profession. The application should therefore state that any future application for GP data should go to NHS Digital.
- The scale and nature of this new processing activity warrants open publication of a Data Protection Impact Assessment.
- PAG noted that at least one of the data processors has a contract with a subsidiary company which is not mentioned on the application. The profession has concerns with the ethical track record of such subsidiary companies that could undermine public and professional trust in the important process of data sharing to support the pandemic (and beyond). PAG request IGARD satisfies themselves that public and professional trust does not become undermined through any GP data sharing with such companies.
- PAG noted the application needs to be specific about the datasets used for linkages; it is appreciated that there may be future emerging datasets that NHSE would like to link to and in such cases the application must be updated. Such review process through DARS/IGARD provides the necessary oversight to protect the public's right to privacy and safeguards against the inappropriate linkage of GP Data.
- PAG noted that any and all derived intellectual property (such as learning models, algorithms, etc) from the GP data must remain the property of NHS England (ie ideally opensourced for

maximum public and professional benefit). This clause should cascade down through any processing arrangements.

- PAG requested IGARD consider whether a Trusted Research Environment (TRE) could satisfy some of NHS England's requirements, rather than providing GP data extracts, thus avoiding unnecessary dissemination of disclosive and sensitive data. In instances where this is not feasible, consideration should be given to sharing smaller defined GP datasets. Wherever possible, the use of a TRE should be encouraged and TRE capabilities extended to support the growing range of research requirements.
- PAG asked what audit arrangements (for example, data processors and use of data sets) were in place and discussed whether there was appropriate reassurance considering the very large number of data processors named. PAG asked IGARD to consider whether a DARS audit of NHS England by NHS Digital would provide further reassurance.

| Attendees | Role | Organisation |
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| Arjun Dhillon | Chair, Caldicott Guardian | NHS Digital |
| Garry Coleman | Associate Director of Data Access | NHS Digital |
| Julian Costello | GP | Representing BMA |
| Amir Mehrkar | GP, Clinical Researcher | RCGP (observer) |
| Marcus Baw | GP | Representing RCGP |
| Peter Short | Clinical Lead GP | NHS Digital |
| Pam Soorma | Secretariat | NHS Digital |

## Appendix C

**Independent Group Advising on the Release of Data (IGARD)**

**Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting**

**held via videoconference, Tuesday, 21 July 2020**

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| **In attendance (IGARD Members):** | Paul Affleck (Specialist Ethics Member) |
| | Dr. Imran Khan (Special GP Member) |
| | Dr. Geoffrey Schrecker (Specialist GP Member / IGARD Deputy Chair) |
| **In attendance (NHS Digital):** | Vicky Byrne-Watts (DARS – item 2.1 & 2.3) |
| | Garry Coleman (DARS – Item 2.4) |
| | Gaynor Dalton (Information Governance – Item 2.3) |
| | Louise Dunn (DARS – item 2.3) |
| | Duncan Easton (DARS – item 2.4) |
| | Karen Myers (IGARD Secretariat – Observer) |
| | Bethan Thomas (DARS – item 2.4) |
| | Kimberley Watson (DARS – item 2.2) |
| | Vicki Williams (IGARD Secretariat) |

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| **2** | **Welcome**<br>The IGARD Deputy 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 business as usual (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 Data Access Request Service (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.<br>**Declaration of interests:**<br>There were no declarations of interest. |
| **2.1** | RECOVERY Trials<br>**Background:** This was a verbal update to the presentation of a number of applications and briefings to the COVID-19 response meetings on the 21 April, 28 April, 5 May, 12 May, 19 May and 7 July. In addition NIC-365354-R3M0Q University of Oxford which had been previously presented to IGARD business as usual (BAU) meeting on Thursday, 11 June 2020 and recommended for approval subject to amendments and advice. |

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| | NHS Digital noted that the University of Bristol was to be added to the University of Oxford application as a Data Processor in order to validate the study outputs and outcomes, and that this would be done via NHS Digital's amendment precedent route.<br><br>**IGARD Observations:**<br><br>IGARD members welcomed the verbal update and proposed next steps to verify the outputs and outcomes from the RECOVERY trials since independent verification was a crucial next step.<br><br>However, it was not clear to IGARD members how the University of Bristol or its statistician had been chosen to undertake the independent verification of outputs and outcomes by the University of Oxford and suggested that a clear outline of the process undertaken to select University of Bristol for the independent verification be included in section 5 of the application.<br><br>In addition a clear narrative should be included as to the role of the University of Bristol and whether they could be considered a Data Controller for this particular processing activity since if the University of Oxford were directing the University of Bristol as a Data Processor and sending onto them specific information, it could be seen that the University of Oxford were directing the University Bristol in the independent verification of outputs and outcomes, and since the whole purpose of asking University of Bristol was to independently review the analysis to ensure the validity of the independent review it was crucial that the University of Bristol were able to analyse all aspects of the study to verify any outputs and outcomes.<br><br>IGARD members also queried if the possibility of the statistician being given access to the data at the University of Oxford had been considered to minimise data flows and storage locations. IGARD members suggested that a clear justification be provided in section 5 of the proposed approach. |
| **2.2** | <u>NIC-374223-P4P4L National Institute for Health Research (NIHR)</u><br><br>**Background:** This was an update to the discussions at the COVID-19 response meetings on the 19 May, 2 June, 9 June and 16 June 2020.<br><br>This was an application from the NIHR BioResource Centre and is a collaboration between clinicians and researchers based at Cambridge and at BioResource centres across the country with thousands of volunteers both with and without health problems who are willing to be approached to take part in research studies to investigate the link between genes, the environment, health and disease.<br><br>The NIHR BioResearch Centre is seeking Hospital Episode Statistics (HES) and Civil Registration data on those patients with inflammatory bowel disease (IBD) for two urgent COVID-19 related research questions.<br><br>NHS Digital noted that they were still awaiting a copy of the updated newsletter from the applicant, that a number of other additional datasets needed to be clarified for inclusion in the application including the Shielded Patient list, and that the name of the applicant needed to be amended throughout the application to refer to the correct entity.<br><br>**IGARD Observations:**<br><br>IGARD welcomed the application and noted the clarifications which needed to be addressed before the application could be presented to a future business as usual (BAU) Thursday meeting. |

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| | IGARD members reiterated their comments that NHS Digital review the full suite of consent materials since the consent materials presented as part of this review started at version 2.1 and the patient information materials at version 3. If no materials prior to these have been used in consenting the cohort this needs to be made clear in the application. IGARD members noted the applicant was to provide an updated newsletter to current participants in order to augment the current consent materials and that this has not been provided as part of this review, but welcomed the approach.<br><br>In addition IGARD members asked that it be clear in section 5 of the application how many participants had been consented on which version of the consent forms / patient information materials and that it be clear throughout the application the cohort sizes and how described.<br><br>IGARD reiterated previous comments that the new newsletter should include an additional paragraph as to how participants can withdraw their consent, but additionally the purpose of the processing, the nature of the processing and the extent that the data was being shared for processing should also be explicitly clear, in addition to the fact that applicant accessed data after the death of a participant.<br><br>IGARD members also reiterated their support of NHS Digital's assessment that the applicant may wish to explore s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG), but noted that HRA CAG would seek to clarify if the cohort could be re-consented.<br><br>IGARD members noted that thought should be given to augmenting the current consent materials for future participants to the study.<br><br>IGARD noted that the '*IBD BioResource Main Cohort PIS V6 220119*' referenced the 'University of Cambridge' and since they were not listed in the application as a Data Controller or Data Processor asked for clarity on the role of the University.<br><br>Noting the question that the researchers were setting about answering from SAGE, IGARD members were not clear how the researchers were addressing those patients who had tested positive for COVID-19 outside of the hospital since it would be important to know, for the purpose of the shielded patient list, and suggested that the applicant may wish to consider Public Health England's Second Generation Surveillance System (SGSS) data and the COVID-19 Hospitalisation in England Surveillance System (CHESS), both datasets held by NHS Digital.<br><br>IGARD members noted the statement that the privacy notice would be updated during 2020 and asked that this statement be quantified as to the date it would be updated, along with updating it to include the current study activities.<br><br>IGARD members reiterated previous comments which, although supportive of the Research Passport system, noted the example honorary contract provided previously (and would flow from the Research passport), did not, for example, provide for the usual safeguards as expected by NHS Digital such as a counter signature of someone with authority over the researcher who could enforce any action required if, for instance, there was a data breach. NHS Digital noted that their policy with regard to counter signatory on honorary contracts had not changed.<br><br>IGARD members noted that the application would be presented to next Thursday's IGARD BAU meeting and that the discussion today was not to pre-empt discussions that would take |

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| | place at that meeting, but a follow up to the points raised at its last presentation at the COVID-19 response meeting and thanked NHS Digital for providing an update. |
| **2.3** | NIC-374190 Genomics England – GenOMICC Study<br><br>**Background:** This was an update to the application and associated supporting documentation presented at the COVID-19 response meetings on the 28 April, 5 May, 12 May, 16 June, 23 June, 14 July 2020, and the application that had been previously deferred by the IGARD business as usual (BAU) meeting on Thursday 25 June 2020.<br><br>**IGARD Observations:**<br><br>There was reference to the consent and commercial model being based on the 100,000 Genomes Project and IGARD reiterated their comments, by way of background, that when this had been last presented to IGARD on the 7 February 2019, IGARD had been unable to make a recommendation in respect of the Genomics Medical Services as the relevant supporting documents were not available, (the consent forms and patient information sheets). Accordingly, while this suite of documents and model may have been in use for some time, IGARD had not previously reviewed it and provided a formal recommendation.<br><br>NHS Digital noted that since this application had been last presented to the COVID-19 response meetings and the IGARD BAU meeting, SD18 had been received '*GenOMICC-GEL COVID Host Genomics Proposal Revised Final*' which outlined, in greater detail than the protocol previously reviewed, the wider COVID-19 study which had support from the Government's Chief Medical Officer (CMO) and in response to the COVID-19 pandemic. NHS Digital also noted that NHS Digital's Information Governance (IG) had reviewed this new document and the updated application and had taken the view that this was now compatible under the Health Service Control of Patient Information (COPI) Regulations 2002 with the purpose outlined in the application that the sublicence model extended to third parties for the purposes of the GenOMICC study. IGARD welcomed this update from IG and the new document provided by the applicant and suggested that this written IG confirmation be uploaded to NHS Digital's Customer Relationship Management (CRM) system as part of the supporting documentation pack.<br><br>Noting that the protocol(s) provided as part of this review did not include the level of detail outlined in the '*GenOMICC-GEL COVID Host Genomics Proposal Revised Final'* document, IGARD members agreed with NHS Digital's analysis that the protocol(s) did not have sufficient ethical approval. IGARD members' main concern was the level of detail in the protocol(s) provided and suggested that these should be augmented to align with the '*GenOMICC-GEL COVID Host Genomics Proposal Revised Final'* document and that these be submitted to the Research Ethics Committees (REC) in England and Scotland.<br><br>IGARD noted that a special condition had been included in section 6 of the application in relation to the 'control' cohort. In the response from the applicant to the deferral point relating to the 100,000 genome cohort, it was not clear what was meant by the term '*booster cases*'. IGARD agreed with NHS Digital that there needs to be clarity as to the role of the 100,000 genome cohort.<br><br>IGARD members and NHS Digital noted that they would be meeting with the applicant to discuss their current suite of consent materials and would feed back to a future meeting.<br><br>**Subsequent to the meeting** |

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| | In addition IGARD members noted at the BAU meeting of IGARD on the 25 June that NHS Digital had confirmed that should the application be significantly updated it would be re-presented to the Profession Advisory Group (PAG). IGARD endorsed this view and felt that before its re-submission to an IGARD BAU meeting it should be re-presented to PAG. |
| **2.4** | <u>NIC-384608-C9B4L NHS England</u><br><br>**Background:** This was a verbal update to the application which was to be presented to the business as usual (BAU) meeting of IGARD on Thursday, 23 July 2020.<br><br>This was a new application for NHS England to receive data in support of the management of the COVID-19 emergency.<br><br>**IGARD Observations:**<br><br>IGARD noted that application was to be presented to the IGARD BAU meeting on Thursday, 23 July 2020 and that it was to be presented following a review by the Profession Advisory Group (PAG) on Wednesday, with a copy of their minute extract appended to IGARD's published minutes.<br><br>IGARD members noted the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update. |
| **3** | <u>AOB</u><br><br>There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting. |