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

**Minutes of meeting held via videoconference 27 August 2020**

| **IGARD MEMBERS IN ATTENDANCE:** | |
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| **Name:** | **Position:** |
| Paul Affleck | Specialist Ethics Member |
| Kirsty Irvine (Chair) | IGARD Lay Chair |
| Dr. Imran Khan | Specialist GP Member |
| Dr. Geoffrey Schrecker | Specialist GP Member / IGARD Deputy Specialist GP Chair |
| Dr. Maurice Smith | Specialist GP Member |
| **IGARD MEMBERS NOT IN ATTENDANCE:** | |
| **Name:** | **Position:** |
| Maria Clark | Lay Member / IGARD Alternate Deputy Lay Chair |
| Prof. Nicola Fear | Specialist Academic Member |
| **NHS DIGITAL STAFF IN ATTENDANCE:** | |
| **Name:** | **Team:** |
| Vicky Byrne-Watts | Data Access Request Service (DARS) |
| Dave Cronin | Data Access Request Service (DARS) |
| Cath Day | Data Access Request Service (DARS) |
| Louise Dunn | Data Access Request Service (DARS) |
| Duncan Easton | Data Access Request Service (DARS) |
| Dan Goodwin | Data Access Request Service (DARS) |
| Richard Hatton | Clinical Informatics (Observer: Items 2.1-2.4) |
| Denise Pine | Data Access Request Service (DARS) (Observer: Item 2.5) |
| Vicki Williams | IGARD Secretariat |

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| **1** | **Declaration of interests:**<br>There were no declarations of interest.<br>**Review of previous minutes and actions:**<br>The minutes of the 20th August 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.<br>**Out of committee recommendations:** |

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| | An out of committee report was received (see Appendix A). |
| **2** | **Data Applications** |
| **2.1** | Lightfoot Solutions UK Ltd: HES data through the Signals From Noise (sfn) tool (Presenter: Kimberley Watson) NIC-359692-Q4X1C<br><br>**Application:** This was an amendment application to include two new additional data fields: encrypted Hospital Episode Statistics (HES) Outpatients (OP) / HES Admitted Patient Care (APC) and pseudonymised Programme Budgeting Category Code (for APC only), a renewal to receive OP and APC for data years 16/17, 17/18, 18/19, 19/20 M13 and 19/20 refresh files until the end of the Data Sharing Agreement (DSA) and an extension to allow the applicant to hold and process data until August 2021.<br><br>Lightfoot Solutions UK Ltd provide the Signals from Noise (sfn) statistical tool to 1) provide access to summary and statistical analysis of patient data to customers with the objective of supporting a greater understanding of patient activity and flow to support activities in order to improve health provision and 2) providing access to summary and statistical analysis of patient data to NHS Commissioning organisations to support healthcare planning and service delivery.<br><br>**Discussion:** IGARD noted and welcomed the approach used by the applicant with regard to statistical process control to look at whether interventions lead to special cause variations and that a suitable rigorous statistical method of analysis was being undertaken.<br><br>IGARD reiterated their comments from when the application had been reviewed at the 21 May 2020 meeting with regard to section 5(d) (Benefits), and noting that the applicant had had the data since 2017, asked that further examples of, and dates of, benefits accruing to patients to support the review of future iterations of the application be provided. In addition, IGARD suggested that the relevant benefits included in section 5(d) which had already been achieved (including the achieved dates) be moved to '*Yielded Benefits*'.<br><br>IGARD reiterated their comments to the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) and suggested that the public facing section be written in a language suitable for a lay reader and that all acronyms upon first use, such as '*HES*' / '*SEFT*', be clearly defined and where necessary an explanation also be given in a language suitable for a lay reader. In addition, IGARD also suggested that a brief summary be included at the start of section 5(a) (Objective for Processing) which outlined the work being undertaken.<br><br>IGARD noted that the Legitimate Interest Assessment (LIA) document provided as part of the review did not make reference to any medical schools, however, section 5(a) referenced the Exeter Medical School, and suggested that both section 1 (Abstract) and section 5(a) be updated to align with the LIA by either removing their reference, or explaining that Exeter Medical School were part of an Academic Health Science Network (AHSN). If, however, medical schools were part of the application, the LIA should be updated appropriately.<br><br>IGARD endorsed NHS Digital's view that on renewal, that NHS Digital may wish to request details with regard to the operation of Lightfoot's HES Group, noting that a Terms of Reference or guiding principles provision had been included as a special condition in section 6 (Special Conditions).<br><br>IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices including, but not limited to, reference to automated decision making. |

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| | **Outcome:** recommendation to approve.<br><br>The following amendments were requested:<br><br>1. To ensure alignment with the LIA, update section 1 and section 5 to ensure any medical schools listed are removed, or the wording amended to reference them being part of an AHSN, if appropriate (or to update the LIA).<br>2. In respect of section 5(d)<br>a. To relocate relevant benefits which have been achieved into '*yielded benefits*' including target dates achieved.<br>b. To expand on the benefits accruing directly to patients.<br>3. To amend section 5 to ensure it is written in Plain English and in a language suitable for a lay reader, including a brief summary at the start of section 5(a).<br>4. To amend section 5 to ensure that all acronyms upon first use be defined and further explained, such as '*HES*'.<br><br>The following advice was given:<br><br>1. IGARD suggested that, on renewal, NHS Digital request details about the effective operation of Lightfoot HES group. |
| **2.2** | <u>University of Oxford: RCGP Research Surveillance Network Observational Research Umbrella (RCGP RSC ORUm) (Presenter: Louise Dunn) NIC-381683-R6R6K</u><br><br>**Application:** This was a new application from the Royal College of General Practitioners (RCGP) and Public Health England (PHE) as joint Data Controllers and University of Surrey and University of Oxford as Data Processors for COVID-19 Second Generation Surveillance System (SGSS) data, NHS 111 online dataset, Secondary Uses Service (SUS) Payment by Results (PbR) Episodes, Emergency Care Data Set (ECDS), Cancer Registration Data, Diagnostic Imaging Data Set (DIDs), Mental Health Services Data Set (MHSDS), SUS PbR Spells, SUS PbR Accident & Emergency (A&E), SUS PbR Outpatients (OP) and COVID-19 Hospitalisation in England Surveillance System (CHESS) data.<br><br>The overall aim of the study is to establish an umbrella agreement for data linkages to support the RCGP RSC to conduct observational epidemiological studies to inform the national public health response and the surveillance function of the RCGP RSC provides a unique platform upon which to build population based observational epidemiological studies.<br><br>**Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 9th June, 30th June and 4th August 2020.<br><br>IGARD observed that the underlying legal basis for some of the datasets requested was linked to the Health Service (Control of Patient Information Regulations) 2002 (COPI) Notice and as that falls way, even if the applicant transitions to another legal basis, it would not cure the issue around the legal basis for those datasets collected under COPI, noting that the underlying datasets were a separate issue.<br><br>NHS Digital had assessed the roles of the all the parties involved in the study and were satisfied a case had been made for the University of Oxford to be a Data Processor, however after a considered discussion, and noting that they were only providing academic input at this stage, IGARD suggested that reference to the University of Oxford as a Data Processor be removed from throughout the application. In addition, and noting the NHS Digital DARS Precedent with regard to the addition of a Data Processor, IGARD suggested that a statement be included in Section 5 (Purpose / Methods / Outputs) that the University of Oxford may join the Data Sharing Agreement (DSA) at a later stage as a Data Processor when the facts |

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| | supported the addition. IGARD also suggested that reference to the University of Surrey as a 'joint Data Controller' be removed, since they had now been assessed as a Data Processor.<br><br>IGARD noted that the data disseminated under this DSA was pseudonymised data but was being treated as confidential patient information, noting that COPI was being relied upon as the legal basis, and suggested that the correct legal basis for NHS Digital to disseminate the data be including in the section 3(b) (Additional Data Access Requested). In addition, and noting the NHS Digital DARS Standard for Data Minimisation, that an indicative cohort size be included in section 3(b) and that the cohort be linked to the time frame under COPI. IGARD also suggested that a special condition be inserted in section 6 (Special Conditions) that a review of the purpose of the DSA be undertaken at the expiry of the COPI notice period. IGARD also noted that data periods for some of the data requested in section 3(b) were not listed and suggested, where appropriate, these be inserted.<br><br>There was a detailed discussion with regard to the data flowing under this application and noting the data was pseudonymised, asked that a clarification be inserted into section 5 that detailed how the processing and dissemination of the data was kept pseudonymised and at no point was it be being re-identified, since it was unclear how NHS Digital would undertake the matching without any re-identification taking place. In addition, IGARD suggested that a narrative be provided in section 5(a) (Objective for Processing) as to how the University of Oxford would achieve their goals with the pseudonymised data disseminated, or if part of a wider project to remove this reference. IGARD also suggested that a delineation be made in section 5 between the research and processing objectives being undertaken in this application from the wider research project, or to remove reference to the wider research narrative if not relevant.<br><br>IGARD noted objective 1(b) in section 5(a) was "*to provide virological evidence on the presence and extend of undetected community transmission of COVID-19 and monitor positivity rates among individuals…*" but were unclear how this would be produced using only pseudonymised data. Also, objective 1(d) which was "*to pilot implementation of a scheme for collection of convalescent sera with antibody profiles among recovered cases of COVID-19 discharged to the community*." and asked how this would be achieved using pseudonymised data.<br><br>IGARD noted reference to a number of legal bases in both section 1 (Abstract) and section 5 and suggested that consistent article 6 and 9 legal bases were listed for both PHE and the RCGP.<br><br>IGARD noted in section 1(c) (Data Processors) that there was reference under the security assurance for the Data Processors for both PHE and University of Surrey to "….***will not** be used for research purposes*" and asked that this be changed to "…***will** be used for research purposes*" to more accurately reflect the application.<br><br>IGARD noted that a scene setting paragraph had been included in section 5(a) which started "*Since the outbreak of COVID-19 in Wuhan, China and the subsequent pandemic…*" and suggested that this be moved to the start of the section, detailing the outbreak of the pandemic and then leading into the objectives for this study.<br><br>IGARD noted in section 3(c) (Patient Objections) that patient objections had not been applied, however, this did not reflect the processing that had been outlined in a number of the supporting documents provided as part of the review, and suggested for consistency that a statement be included in section 3(c) detailing what opt outs had been applied and when they had been applied.<br><br>IGARD noted in section 5(d) (Benefits) that no yielded benefits had been listed but that in section 5(c) (Specific Outputs Expected, including target dates) that work had been |

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| | undertaken previously, and suggested that either reference to the previous work undertaken be removed from both sections, or a brief explanation be included of the benefits accrued over the preceding years. In addition, the link between the benefits outlined and the objectives should be clearly explained.<br><br>IGARD noted and endorsed NHS Digital's review that the applicants did **not** meet NHS Digital's Standard for privacy notices and asked that NHS Digital provide a verbal update of the progress made to IGARD with regard to the two privacy notices. In addition, a special condition should be inserted into section 6 that the applicants would publish General Data Protection Regulation (GDPR) compliant privacy notices and within one month of signing the DSA. Section 4 (Privacy Notice) should also be updated to reference the Data Controllers in plural, reflecting there were two Data Controllers.<br><br>IGARD noted that a number of ethics supporting documentation had been provided as part of the review, however since they were not relevant, suggested reference to them be removed from section 1 (Abstract) or an explanation provided as to their inclusion.<br><br>IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent (with the exception of adding University of Oxford as a Data Processor only, which would be suitable for the Precedent route).<br><br>**Outcome:** recommendation to approve subject to condition<br><br>1. In respect of the data flows:<br>a. To provide narrative in section 5(a) how University of Oxford will achieve their goals with pseudonymised data, or remove reference to any goals that are part of a wider project,<br>b. To clarify in objective 1(b) in section 5(a) how the "*virological evidence*" will be produced using pseudonymised data,<br>c. To clarify in objective 1(d) in section 5(a) how the "*convalescent sera*" objective will be achieved using pseudonymised data,<br>d. To clearly delineate in section 5 the research and processing objectives of using the data under this application from the wider research project, or to remove the wider research narrative,<br>e. To clarify in section 5 how with the processing and dissemination of data that is being undertaken, how the data is kept pseudonymised and at no point re-identified.<br><br>The following amendments were requested:<br><br>1. To amend the application throughout to remove reference to the University of Oxford as a Data Processor.<br>2. To update section 5 to note that the University of Oxford may join the DSA at a later data as a Data Processor, and when the facts support the addition.<br>3. To amend the application throughout to remove reference to the University of Surrey as a 'joint Data Controller'.<br>4. In respect of section 3(b):<br>a. To include an indicative cohort size and that the cohort is linked to the time frame under COPI.<br>b. To note the correct legal basis for NHS Digital to disseminate data.<br>c. To insert the data periods for each dataset requested, and as available.<br>5. To update section 1 and section 5 to ensure RCGP and PHE have consistent article 6 and 9 legal bases. |

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| | 6. To amend section 1(c) to be clear for PHE and University of Surrey that the data **will** be used for research purposes, under this DSA.<br>7. To provide an analysis in section 3(c) as to what opt outs have been applied and when.<br>8. To update section 4 to reflect that there are two Data Controllers.<br>9. To insert a special condition in section 6 that within 1 month of signing the DSA, both Data Controllers will have published a GDPR compliant privacy notice.<br>10. To move the explanatory scene setting paragraph with regard to the outbreak to the start of section 5(a).<br>11. In respect of section 5(d):<br>a. To clearly link the benefits outlined to the objectives listed under this DSA,<br>b. To provide a brief explanation of the benefits accrued over the preceding years or remove reference to the prior work undertaken in sections 5(c) and 5(d).<br>12. To provide an explanation in section 1 of the inclusion of ethics SDs, or if not relevant to this DSA, to remove the SDs.<br>13. To insert a special condition in section 6 that a review of purpose of the DSA will be undertaken at expiry of COPI notice period.<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, including the SIRO Precedent (with the exception of adding University of Oxford as a Data Processor only, which would be suitable for the Precedent route).<br><br>**ACTION:** NHS Digital to provide a verbal update to IGARD by no later than the last BAU meeting of IGARD in October 2020 with a progress update of the two privacy notices.<br><br>It was agreed the conditions would be approved OOC by IGARD Members |
| **2.3** | <u>NHS Blood & Transplant (NHSBT): R11, R11.1, R11.2 – convalescent plasma programme (serum trial) (Presenter: Vicky Byrne-Watts) NIC-372791-X0H3Q</u><br><br>**Application:** This was an amendment application to include GPES Data for Pandemic Planning & Research (GDPPR) data in order to support NHSBT in compiling a list of potential donors who can donate their convalescent plasma as a potential treatment for COVID-19, to help with the ongoing pandemic.<br><br>Previous data releases under v0 and v1 of this agreement for COVID-19 Hospitalisation in England Surveillance System (CHESS) data, Secondary Uses Services (SUS) Admitted Patient Care (APC), Personal Demographic Service (PDS, and COVID-19 Second General Surveillance System (SGSS) data, had been facilitated and finalised by signed letters from the NHS Digital Information Governance (IG) directorate, and was to provide contact details for individuals who fit the criteria for collection of convalescent plasma which is being explored as a possible treatment for COVID-19.<br><br>The GDPPR data request is to support contacting individuals who are believed to have had COVID-19 to discuss with the individual if they wish to donate convalescent plasma, whether the individual is eligible to donate plasma and to book an appointment. NHSBT is already in receipt of pillar 1 and pillar 2 data. The work will continue to support clinical trials.<br><br>**Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 28th July and 18th August 2020. |

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| | IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 19th August 2020.<br><br>IGARD noted that the previous datasets released as part of this application had been approved by NHS Digital and IGARD was not providing a view on those datasets and was therefore only considering the GDPPR dataset amendment request.<br><br>Tests in the UK are carried out through a number of different routes and Pillar 3 data is serology testing to show if people have antibodies from having COVID-19 and IGARD reiterated their previous observations raised at the COVID-19 response meeting and asked why the applicant was not requesting pillar 3 data from the relevant authority holding that data, noting that this data was **not** held by NHS Digital, since it was a potential rich and highly relevant source of data which did not seem to have been considered. IGARD asked that a suitable justification be provided as to why the applicant was not requesting pillar 3 data and that in addition to acknowledging the existence of pillar 3 data in section 5(a) (Objective for Processing), that an explanation be provided of what pillar 1 and pillar 2 datasets covered and in a language suitable for a lay reader. In addition, IGARD also suggested that a brief acknowledgment be made to the Cochrane Collaboration which highlighted the urgent and critical need for convalescent plasma trials.<br><br>IGARD observed that in over 22,000 of the calls made, half the individuals contacted did not wish to continue the conversation with the call centre. Given this significant number of citizens not wishing to engage with a *"cold caller"*, IGARD suggested that the applicant consider other means of contacting eligible individuals – for example a letter from a local CCG or GP or other NHS body on NHS-headed paper. Increasing the number of citizens who wish to learn about the convalescent plasma trial this way would in turn reduce the need to access the GDPPR dataset. It was therefore suggested that NHSBT consider consulting with patient representatives at all stages of the study, particularly in the designing of call centre scripts and mailouts to potential donors of convalescent plasma. In addition, IGARD noted that the script used by the 3rd party contractor included a misleading statement in the call centre script: "*Please rest assured that we have not and will not share your information outside NHS Blood and Transplant*" " and suggested its removal or amendment to be clear that the call centre was a third party contractor, not part of NHSBT.<br><br>IGARD noted in NHS Digital's Information Governance (IG) letter of release that had been provided as part of the review, that a condition had been inserted at point 8: *"The Recipient will notify NHS Digital if it receives any complaints from individuals it contacts and the parties agree that if there are complaints they will review this data sharing arrangement and if appropriate, NHSBT will cease processing the Disclosed Data for the Agreed Purposes."* However IGARD suggested that further thought was given to the requirements of the letter stipulating that a full review be undertaken of the study each time a complaint was received, since in practice that might be a disproportionate response for the applicant.<br><br>IGARD noted the rigour undertaken by NHS Digital in assessing Teleperformance's contractual arrangements and suggested that this good practice be used for all relevant applicants under COPI to ensure the appropriate contractual arrangements for data processors were in place.<br><br>IGARD noted in section 3 (Data Sets Held / Requested) and Section 5 (Purpose / Methods / Outputs) reference to "…*anyone with an S-flag*…" and asked that a brief explanation of the 'S-flag' be provided. |

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| | In addition, IGARD asked that it be clearly set out in section 5 how much data would be flowing from the relevant SNOMED codes, since the number of codes was in excess of 200, and which linked to NHS Digital's DARS Standard on Data Minimisation.<br><br>Noting that the applicant had recruited over 5,000 plasma donors, IGARD asked that section 5(d) (Benefits) be updated with the yielded benefits that had accrued to date via the processing that had been undertaken.<br><br>IGARD noted the Profession Advisory Group (PAG) comments (see Appendix B) and asked that the analysis in section 1 (Abstract) be updated to note that consent was being requested for plasma to be *taken*.<br><br>IGARD noted that section 1 should also be updated in reference to the General Data Protection Regulation (GDPR) Article 9 legal basis to confirm that there is a suitable individual within NHSBT that will be responsible for the data, in order to satisfy section 11(1) of the Data Protection Act (DPA) 2018.<br><br>IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices.<br><br>**Outcome:** recommendation to approve subject to the following condition.<br><br>1. To provide an appropriate justification of why the applicant is not applying for pillar 3 data from the relevant body.<br><br>The following amendments were requested<br><br>2. In respect of section 5:<br>a. To explain in section 5(a) what pillar 1 and pillar 2 datasets cover and to acknowledge the existence of pillar 3, and in a language suitable for a lay reader<br>b. To note the Cochrane Collaboration which highlighted the need for the convalescent plasma trial,<br>3. To update section 5(d) with the yielded benefits accrued via the processing undertaken.<br>4. To provide an explanation in section 3 or 5 with regard to '*S flag*'.<br>5. To clearly set out how much data will be flowing from relevant SNOMED codes in section 5.<br>6. To update the analysis in section 1 with regard to the PAG comment on patient consent (consent for plasma to be ***taken***).<br>7. To amend section 1 in reference to the article 9 legal basis analysis to confirm there is a relevant individual within NHSBT that will be responsible for the data to satisfy section 11(1) of DPA 2018.<br><br>The following advice was requested:<br><br>1. IGARD suggested that NHSBT consult with patient representatives at all stages of this study, particularly in designing call centre scripts and mailouts.<br>2. IGARD suggested that the call centre script be amended to be clear that where they reference "…*Please rest assured that we have not and will not share your information outside NHS Blood and Transplant* " that it be amended since the call centre is a third-party contractor.<br>3. IGARD suggested that further thought was given to the requirements of letter stipulating that a full review undertaken of the study each time a complaint is received.<br><br>It was agreed the conditions would be approved OOC by IGARD Members |

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| **2.4** | University of Sheffield: Pandemic Respiratory Information Emergency System Triage (PRIEST) Study (Presenter: Cath Day) NIC-377644-X9J4P<br><br>**Application:** This was a new application for GPES Data for Pandemic Planning & Research (GDPPR), Demographics data, Emergency Care Data Set (ECDC), Hospital Episode Statistics (HES) Admitted Patient Care (APC), Civil Registration (deaths) data, and HES Critical Care (CC).<br><br>The PRIEST study is a National Institute for Health Research (NIHR) funded project aimed at evaluating and optimising the triage of people using the emergency care (111 or 999 calls, ambulance conveyance or hospital emergency department) with suspected respiratory infections during the COVID-19 pandemic. The PRIEST study was originally the PAndemic Influenza Triage in the Emergency Department (PAINTED) study which was developed to evaluate emergency department triage methods during a pandemic. Research in this area is urgently needed to determine the accuracy of pre-hospital and emergency department triage decision during the current COVID-19 pandemic and explore whether they could be improved.<br><br>NHS Digital noted that section 1 (Abstract) would be updated to include reference to any NHS Digital information governance (IG) directorate feedback.<br><br>**Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 4th August 2020.<br><br>IGARD also noted that this application had also been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on the 19th August 2020.<br><br>IGARD noted that this was a particularly well-written application and thanked the efforts undertaken by both the applicant and NHS Digital.<br><br>IGARD queried the progress made to address the specific conditions of support which were set out in the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditional letter of support, dated 17 July 2020. Noting that the applicant would have to provide written feedback to HRA CAG and within three months of the issue date of the letter, asked that a written update be provided, such as an unconditional letter of support from HRA CAG, and that it be uploaded to the Customer Relationship Management system as a future supporting document. IGARD noted that without unconditional support in place, the support from HRA CAG would fall away on the 17 October 2020 and the applicant would not have the appropriate legal basis in place.<br><br>IGARD queried the data flows under this application and why the data flowing from NHS Digital to the University of Sheffield was identifiable, and noting NHS Digital's DARS Data Minimisation Standard, suggested that a clear explanation be provided as to why the data could not be pseudonymised prior to dissemination.<br><br>IGARD noted that section 3(b) (Additional Data Access Requested) that the data minimisation column should be updated to include reference to the data being minimised by code cluster, not just minimised by the cohort.<br><br>IGARD noted that the special condition wording in section 6 (Special Conditions) should be updated to include the latest agreed wording with regard to the Health Service Control of Patient Information (COPI) Regulations 2002 sunset clause referencing the notice expiration or review.<br><br>IGARD noted in section 5(d) (Benefits) reference to 'risk stratification' and suggested that an explanation be provided that the potential risk stratification tool would be used by clinicians to |

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| | assist in the appropriate triage or assessment of patients, rather than by way of automated decision making process.<br><br>**Outcome:** recommendation to approve which aligned with conditional CAG support, subject to condition:<br><br>1. In respect of the HRA CAG conditional support (which falls away in October 2020):<br>a. To provide a written update setting out progress made to address the specific conditions of support,<br>b. To upload a copy of the documentation to CRM.<br><br>The following amendments were requested:<br><br>2. To provide an explanation as to why the data cannot be pseudonymised prior to the dissemination from NHS Digital.<br>3. To update section 3(b) data minimisation column to include the code cluster.<br>4. To update section 5(d) to explain that the potential risk stratification tool will be used by clinicians to assist in the appropriate triage or assessment of patients.<br>5. To update section 6 to include the latest agreed special condition wording with regard to the COPI notice expiration or review.<br><br>It was agreed the conditions would be approved OOC by IGARD Members. |
| **2.5** | <u>i5 Health Ltd: NHS Commissioning support (Presenter: Dave Cronin) NIC-14709-Z2H2R</u><br><br>**Application:** This was an amendment application to 1) add Emergency Care Data Set (ECDS) as a data product for a cross over M13 data period as Hospital Episode Statistics (HES) Accident & Emergency (A&E) data stopped at M12 2019/20 (ECDS is a direct replacement for HES A&E data), 2) update the application to include reference to a newly created Coronavirus Health Risk Calculator, and 3) to provide further justification for the request for 7 years of data on a rolling basis and renewal application to extend the Data Sharing Agreement (DSA) to March 2021.<br><br>i5 Health analyses relevant activity data to identify utilisations of Non-Medical Prescribing (NMB) practitioners in various health care settings to enable them to measure the impact of NMP has, or, if introduced more widely, will have on different health economies.<br><br>NHS Digital noted inconsistencies in the naming convention with regard to i5 Health Limited and that the application had been updated throughout to ensure consistency.<br><br>NHS Digital also noted that the data minimisation column in section 3(b) (Additional Data Access Requested) was blank for the ECDS data and that this had now been populated.<br><br>**Discussion:** IGARD noted that the applicant appeared to be using secondary care data to produce a tool to be used in a primary care setting and suggested that the applicant explore using Primary Care Data from NHS Digital or elsewhere, and that it should be made clear in section 5(a) (Objective for Processing) that there were inherent limitations of the Risk Calculator tool which used secondary care data for primary care purposes.<br><br>There was a detailed discussion with regard to the Risk Calculator tool outlined in the application and IGARD noted that although an individual may not be re-identified, that the application should be updated throughout to state that no re-identification of individuals was being undertaken under this application. In addition it should also be clearly stated in section 5(a) (Objective for Processing) that the tool '…*may be used by clinicians to support assessment…*" since the current wording indicated that it may be the tool undertaking that assessment. |

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| | IGARD noted that since the application had been submitted that some of the wording in section 5(a) appeared out of date and suggested it be updated, such as removing reference to "…*by early July*…".<br><br>IGARD noted in section 5(d) (Benefits) reference to "…*saving hundreds of thousands of pounds*…" and asked that this be removed, since it would likely be a reduced transactional cost, as opposed to a real-world money saving.<br><br>IGARD noted that i5 Health was analysing relevant activity data to identify utilisations of NMB practitioners in various health care settings but asked that a further explanation of the activities undertaken be clearly outlined and what outputs and benefits i5 hoped to achieve, and in addition the benefits that will flow from the analysis of using NMP in section 5 (Propose / Methods / Outputs).<br><br>IGARD noted that North East London (NEL) Commissioning Support Unit (CSU) had selected medical records of circa 4 million Londoners processed through i5 health system's tool and asked that an analysis of the tools yielded benefits in relation to the use with these records be included in section 5(d). Noting that a number of the yielded benefits appeared to be expected measurable benefits, IGARD also suggested they be moved. In addition IGARD noted that on return they would expect to be provided with a detailed analysis of the outputs and yielded benefits achieved with the data received under this application.<br><br>IGARD noted that this application would not be suitable for NHS Digital's Precedent route and that they would wish to review this application when it comes up for renewal, extension or amendment.<br><br>**Outcome:** recommendation to approve.<br><br>The following amendments were requested:<br><br>1. In respect of section 5(a):<br>a. To be clear that the calculator "*may be used by clinicians to support assessment*".<br>b. To update the text to reflect the current status of the application such as, but not limited to, removing reference to '…*by early July*…".<br>c. To make clear that there are inherent limitations of the tool which uses secondary care data for primary care purposes.<br>2. In respect of section 5(d):<br>a. To remove reference to "…*saving hundreds of thousands of pounds*…",<br>b. To provide an explanation of the activities that i5 carry out around NMP and what benefits and outputs they expect to achieve,<br>c. To provide an explanation with regard to the benefits that will flow from the analysis of using NMP,<br>d. To provide an analysis of the tool's yielded benefits in relation to the use with NEL CSU medical records,<br>e. To move the appropriate benefits from the '*yielded benefits*' into '*expected measurable benefits*'.<br>3. To be clear throughout the application that there will be no re-identification of individuals.<br><br>The following advice was given<br><br>1. IGARD noted that the applicant appeared to using secondary care data to produce a tool to be used in a primary care setting and suggested that the applicant explore using Primary Care Data from NHS Digital or elsewhere. |

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| | 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment.<br>3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.<br>4. IGARD noted that on return that a detailed analysis of that outputs and yielded benefits achieved should be provided. |
| **2.6** | <u>NHS Bristol Somerset & Gloucester CCG: making CCG operational planning more robust by using a large activity sample size to derive analytics (Presenters: Duncan Easton / Dan Goodwin) NIC-238370-G8Z6V</u><br><br>**Application:** This was an extension application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Outpatient (OP) and HES Accident & Emergency (A&E) for the purpose of analysing pseudonymised non-patient level data to derive empirical problematic distributions for the processes of interest and from these fit theoretical distributions which can be used in simulation modelling and statistical analysis of existing and proposed patient pathways. No further data will be disseminated under this agreement.<br><br>**Discussion:** IGARD noted in section 4 (Privacy Notice) that the privacy notice **did not** meet the General Data Protection Regulation (GDPR) criteria, however section 1 (Abstract) and relevant supporting documentation indicated the privacy notice **did** meet GDPR requirements and suggested section 4 be updated appropriately.<br><br>IGARD noted the good work being undertaken by the applicant and how the applicant was proposing to work with other CCGs, and suggested that sections 5(c) (Special Outputs Expected including target dates) and 5(d) (Benefits) be updated further to reflect this positive approach.<br><br>IGARD noted the helpful description in section 5(a) (Objective for Processing) of the modelling being undertaken, which had effective and clear communications and was well set out.<br><br>IGARD also noted that a link to the work had been included in section 1 (Abstract) and suggested that this be copied to section 5(d) (Benefits) so that when published on the release register, members of the public could access easily.<br><br>IGARD noted in section 5(c) reference to 'R Shiny *dashboards*' and asked that the narrative be updated to more accurately describe R Shiny *dashboards* as a '*tool for interactive data visualisation*'.<br><br>In addition, IGARD suggested that section 5(d) be updated to remove reference to managing budgets and suggested that the wording be updated to more accurately reflect that it is "…*hoped to optimise the use of the budget*…".<br><br>**ACTION:** Separate to this application, IGARD requested that NHS Digital bring to a future IGARD meeting the relevant analysis with regard to the numbers of processing and storage locations in this type of application.<br><br>**Outcome:** recommendation to approve<br><br>The following amendments were requested:<br><br>1. To update section 5(c) and 5(d) to promote the good work being undertaken by the applicant.<br>2. To update the '*"R Shiny dashboards"* reference in section 5 to explain these are a tool for interactive data visualization.<br>3. To update section 5(d) to note that it is "…*hoped to optimise the use of the budget*…" |

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| | 4. To update section 4 to confirm the privacy notice **does** comply with GDPR. |
| **2.7** | <u>Worcestershire County Council: COVID-19 predicting future adult social care and A&E admissions (Presenters: Duncan Easton / Dan Goodwin) NIC-385550-Y8T2M</u><br><br>**Application:** This was a new application for pseudonymised Mental Health Services Data Set (MHSDS), Secondary Use Service (SUS) for Commissioners, Adult Social Care, Community Services Data Set (CSDS) and Maternity Services Data Set (MSDS), for the purpose of developing a Predictive Model that will answer COVID-19 response related questions, to enable Worcestershire County Council to work better with its population and target communications and support.<br><br>Worcestershire County Council have been working with their partner AT Provider and PredictX over the past year to look at how analysing trends can help predict future adult social care and A&E admissions through the way someone uses their assistive technology equipment. In light of COVID-19 and the changes to the way people are living and the support they are receiving the county council have reviewed this project.<br><br>**Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 11th August 2020 and had been presented to IGARD business as usual (BAU) for advice on the 13th August 2020.<br><br>IGARD noted that this was an innovative use of the data for predictive modelling.<br><br>IGARD noted reference in section 5(a) (Objective for Processing) to "*Worcestershire County council require a number of different datasets including the shielded patient list*…" and noting that this was a restricted dataset that the applicant had not requested, asked for clarification of where the applicant had obtained the Shielded Patient List (SPL) data from and how they were intending to use the SPL data. In addition, and noting the parameters laid out in the COVID-190 Public Health Directions 2020 (COVID-19 Directions), asked for confirmation that any activity with the SPL data was as set out in the appropriate Direction.<br><br>Noting the Social Care Data Direction 2017, which had not been provided as part of the review, IGARD asked that clarification be given in section 1 (Abstract) as to how the Direction was being used to identify the relevant cohort linkage outlined in the application. In addition, and noting the parameters laid out in the Direction, to confirm that the processing of the data under this Data Sharing Agreement (DSA) was permitted.<br><br>IGARD suggested that section 5(d) (Benefits) be updated to be clear that there will be no re-identification of individuals, although characteristics that define particular cohorts will be identified.<br><br>IGARD were unclear if PredictX was the trading name of PI Limited or a tool of PI Limited, and asked that an explanation be provided in section 5 (Purpose / Methods / Outputs) that PredictX was indeed the trading name for PI Limited and to ensure consistent use of language throughout the application. In addition, confirmation should be provided if there was any commercial element to the activities undertaken or if it was just tools being provided by PI Limited, since it was not clear in the application or supporting documentation provided.<br><br>IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) such as "*level 1, level 2*" and suggested the public facing section be written in a language suitable for a lay reader and technical terms used only where necessary.<br><br>IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. |

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| | **ACTION:** IGARD noted, and separate to this application, that NHS Digital should always provide a copy of the relevant Direction relied upon as a supporting document.<br><br>**Outcome:** recommendation to approve subject to the following condition<br><br>1. In respect of the reference to the shielded patient list (SPL) and updating section 5(a):<br>a. Noting the applicant has not requested SPL data from NHS Digital, to clarify where they have obtained the SPL data from,<br>b. To clarify how they are intending to use the SPL data,<br>c. To confirm that any activity with the SPL is within the permitted parameters of the SPL Direction.<br><br>The following amendments were requested:<br><br>1. In respect of the Social Care Data Direction 2017:<br>a. To clarify in section 1 if the Direction is used to identify the relevant cohort for linkage,<br>b. To confirm that the processing under this DSA is permitted under the Direction.<br>2. In respect of PI Limited and PredictX:<br>a. To explain in section 5 if PredictX is the trading name for PI Ltd and to use consistent language throughout.<br>b. To confirm if there is a commercial element to this activity or if it is just using the tools provided<br>3. To updated section 5(d) to be clear that there will be no re-identification of individuals, although characteristics that define particular cohorts will be identified.<br>4. To amend section 5 to ensure the use of technical jargon is used only where necessary such "*level 1, level 2*"<br><br>It was agreed the conditions would be approved OOC by IGARD Members |
| **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 25th August 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>NIC-15625-T8K6L - Medicines and Healthcare Products Regulatory Agency (MHRA)</u><br><br>The application was recommended for approval by way of a majority vote of five, with one member abstaining on the 16th July 2020, for the amendment to link CPRD data with ICNARC data only, and without prejudice to a number of open issues that should be addressed before it |

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| | returns to IGARD for a full review. The majority recommendation to approve is subject to the following amendments:<br><br>1. To update section 5(e) to reflect the use of the sub-licence of the NHS Digital data, for example, that pharmaceutical or other commercial companies will sub-licence the data and how they will benefit from the data to advance their commercial aims (NHS Digital Commercial Purpose Standard refers).<br>2. To update section 2(c) to reflect the special condition that SGSS and CHESS data may not be accessed outside the EEA.<br>3. To replace reference to "*consenting* GP practices" with "*participating* GP practices", or similar.<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>3. IGARD suggested uploading to NHS Digital's CRM system, any NHS Digital IG advice relating to CPRD's sub-licensing arrangements.<br><br>The open issues for resolution by renewal include (but are not limited to):<br><br>1. The fundamental nature of the data received by CPRD and then shared under sub-licence (e.g. identifying, pseudonymised, anonymised or anonymous).<br>2. The inconsistency between the description of the data within the application and as described on the CPRD website.<br>3. Reference to SGSS and CHESS data and the geographical limitations on their use; the ability of CPRD to rely on Reg 3 of COPI for sub-licensing and the significance of the limit to EEA.<br>4. The issue of transparency for GP practice patients and the accuracy of the statements made within the relevant transparency materials.<br><br>NHS Digital noted that they wished to propose a change to amendment 1, from the above, to the following:<br><br>1. To include section 5(e) for following statement: Under the sub-licence arrangements set out in this agreement, commercial companies (including the life science sector) are permitted to use the data for public health research and surveillance only to the benefit of health and social care as set out in section 5 of the agreement. In so doing, they might derive a commercial benefit.<br><br>Notwithstanding that amendments are 'amber conditions' as set out in the IGARD Terms of Reference and associated standard operating procedures for the SIRO, or delegate authority to approve, IGARD on this occasion and without setting precedent, noted the amendment without objection. |
| **5.2** | IGARD Briefing paper: Breast & Cosmetic Implant Registry<br><br>The Breast & Cosmetic Implant Registry briefing paper had been previously presented to IGARD on the 30th July 2020. Ahead of potential applications for the data, a finalised updated briefing note was received.<br><br>IGARD noted the content of the briefing note and thanked NHS Digital for providing the finalised paper. |

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| **5.3** | Commercial Standard<br><br>NHS Digital noted that the DARS commercial standard had been substantially redrafted and it was agreed that a mini workshop be included on the IGARD business as usual agenda on the 17th September to finalise the standard, as per the agreed process. |
| **5.4** | GDPPR CCG Pseudo Precedent & Templated wording<br><br>The initial briefing paper with regard to GDPPR data had been presented to the COVID-19 response meeting on the 21 April 2020, and further considerations of the templated wording at the 9th June and 30th June COVID-19 response meeting.<br><br>In addition there was informal engagement with regard to the CCG and Local Authority templated applications at the business as usual (BAU) IGARD meeting on the 28 May 2020 and consideration at the 6th August BAU meeting of 3 templated CCG applications for GDPPR data (NIC-387297-J5L7M NHS North Lincolnshire, NIC-384781-J8H2K NHS Wakefield CCG and NIC-387358-H3Z2J NHS Birmingham and Solihull CCG).<br><br>The CCG GPES GDPPR pseudo templated content had been reviewed at the GPES GDPPR – Profession Advisory Group (PAG) on the 8th July (notes from that meeting attached to the IGARD minutes from the 9th July 2020), on the 15th July 2020 (notes of that meeting attached to the minutes of the 6 August), and tabled on the 5th August 2020 with no minutes produced.<br><br>IGARD provided a number of small but substantial comments with regard to the Precedent cover sheet and templated wording and looked forward to receiving the finalised version, once it had followed DARS's approved process path and before applications were approved under the Precedent. |
| **5.5** | IGARD quoracy due to COVID-19<br><br>In light of the ongoing situation with COVID-19 and a note under AOB within the 2 April 2020, IGARD members reconfirmed that in-meeting quoracy may be temporarily reduced to three members (from four members) which must include a Chair and at least two specialist members in the event that COVID-19 impacts on a member's ability to dial into a meeting (due to illness or caring for a householder member) and to support those members who have other roles linked to the COVID-19 response. This relates to COVID-19 only. This will continue to be reviewed as and when required, but no less than monthly and in response to new guidance that is released and to ensure continued business continuity.<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 21/08/20

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-381383-Z9F2P | Department for Transport | 30/07/20 | 1. In respect of the additional COVID-19 purpose:<br>a) To provide confirmation if the additional COVID-19 purpose needs to be expressly included in the application.<br>b) If the additional COVID-19 purpose is distinct, to submit an amendment application to HRA CAG.<br>c) (If condition 1(b) is actioned): To provide appropriate evidence that the HRA CAG amendment application has been submitted.<br>2. To insert a special condition in section 6 stating that within 1-month a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published. | IGARD Members | Quorum of IGARD Members | The application now states:<br>The privacy notice will be updated to include the following detail within 1 month of the DSA being signed:<br>*~ The purpose of the processing*<br>*~ The categories of personal data obtained (if the personal data is not obtained from the individual it relates to).*<br>*~ The retention periods for the personal data.*<br>*~ The source of the personal data*<br>This means that point 8 in the original notice will still be deficient i.e. "*8. The recipients or categories of recipients of the personal* |

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| | | | | | | *data. No*." We'd suggest that it would be simpler to add that "a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published". |
| NIC-374223-P4P4L | National Institute for Health Research (NIHR) Bioresource | 06/08/20 | 1. To make clear throughout the application the process of re-identification and how this aligns with the re-identifications instances that patients were informed of via the PIS. | IGARD Chair | IGARD Chair | N/A |

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

## Appendix B

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

## Record of feedback: Wednesday, 19th August 2020

| **Application: DARS-NIC-372791-X0H3Q-v2.3**<br>**Organisation name: NHSBT Convalescent Plasma Trial**<br>**Profession Advisory Group Agenda item: 3** |
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| 1. PAG requested sight of the SNOMED codes that were being used to minimise the data, and based its comments on the belief that data minimised to identifying individuals that may be suspected of having had COVID. PAG recommended that the dataset be reviewed to ensure that the code listing was appropriate. PAG are concerned that if the wrong cohort are selected this would be incompatible with the principle of "no surprises" and that NHSBT are responsible for any complaints.<br>2. PAG note the research and therapeutic potential of the application and that patient consent is central to any participation.<br>3. PAG members note the importance of the application and its work for addressing a potential therapy at the time of a pandemic. PAG support the application if the above issues are addressed. Please note this is not a professional endorsement of the Trial from BMA or RCGP, as this is beyond the scope of PAG. |

| 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 |
| Julian Costello | GP | RCGP |
| Pam Soorma | Secretariat | NHS Digital |

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

Record of feedback: Wednesday, 19th August 2020

| **Application: DARS-NIC-377644-X9J4P**<br>**Organisation name: University of Sheffield**<br>**Profession Advisory Group Agenda item: 2** |
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| 1. PAG noted that the request for all the GDPPR (and not minimised by SNOMED code). PAG felt that the application needed to justify why the entirety of the dataset was required (e.g. could it perhaps only require long term condition data).<br>2. PAG felt it would be helpful to state the size of the cohort within the application.<br>3. If the above are address PAG members are in support of this application. |

| 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 |
| Julian Costello | GP | RCGP |
| 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, 25 August 2020**

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| **In attendance (IGARD Members):** | Paul Affleck (Specialist Ethics Member) |
| | Kirsty Irvine (IGARD Lay Chair) |
| | Dr. Imran Khan (Specialist GP Member) |
| **In attendance (NHS Digital):** | Vicky Byrne-Watts (DARS – item 3.2) |
| | Louise Dunn (DARS – item 3.3 – 3.5) |
| | Duncan Easton (DARS – item 3.1) |
| | Liz Gaffney (DARS – item 2 & 3.1) |
| | Vicki Williams (IGARD Secretariat) |
| **In attendance (external):** | Emily Cross (IBM (external) – item 2 only) |

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| **1** | **Welcome**<br>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 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** | <u>IBM update</u><br>IGARD members were given a brief update to the IBM work underway in NHS Digital including improvements to the customer experience and current projects. It was agreed that this would be a weekly update to the COVID-19 response meeting.<br>IGARD members thanked IBM and NHS Digital for the update and reiterated their previous suggestion that IGARD should be included early in any process or drafting changes including, but not limited to, application checklists, standards and precedents. |
| **3.1** | <u>GDPPR CCG Pseudo Precedent</u><br>**Background:** This was an update to the briefing paper presented to the COVID-19 response meeting on the 21 April 2020 and further considerations of the templated wording at the 28th May, 9th June and 30th June, and in addition the informal engagement with regard to the CCG and Local Authority templated applications at the BAU IGARD meeting on the 28 May 2020 and consideration by IGARD at the 6th August BAU meeting of 3 templated CCG applications |

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| | for GDPPR data (NIC-387297-J5L7M NHS North Lincolnshire, NIC-384781-J8H2K NHS Wakefield CCG and NIC-387358-H3Z2J NHS Birmingham and Solihull CCG).<br><br>NHS Digital noted that the precedent and templated application wording would be presented to the Professional Advisory Group (PAG) for information only on Wednesday, 26th August 2020 and asked if the same item could be tabled under AOB at this Thursday's business as usual (BAU) IGARD Meeting.<br><br>In addition NHS Digital noted that they had sought further advice from the Information Governance (IG) directorate but were still awaiting feedback.<br><br>**IGARD Observations:**<br><br>IGARD members noted the inclusion of the AOB item for the precedent and templated wording at Thursday's BAU meeting.<br><br>IGARD members noted that they had made a number of small but significant suggestions to amend the text in the templated wording, in addition to the points raised on the individual CCG applications presented to IGARD, however not all were reflected in the documentation presented. IGARD members asked that any item presented at AOB on Thursday was updated to include all past suggested text changes to ensure that when the precedent was applied the CCG's were using the correct templated wording application, which formed the basis of the Data Sharing Agreement (DSA). In addition, the documentation provided as part of the BAU review should include all relevant supporting documents required for review by IGARD (for example, any relevant Directions relied upon).<br><br>IGARD members noted that some of the wording within the precedent cover sheet was generic but should be updated to include, but not limited to:<br><br>• Include a copy of the specific risk criteria document or to define the term 'specific risk criteria' and refer to that stand alone document,<br>• to remove the wording in exclusion criteria: "…*falling under this precedent*…"<br>• to ensure all typos and bulleted points are corrected,<br>• to remove reference to "…*above*…" when referencing the data, since this precedent is for GDPPR data which cannot be linked.<br>• To ensure the version control section was fully updated. |
| **3.2** | <u>NIC-381719-L6D2H King's College Hospital NHS Foundation Trust London and Guys & St Thomas'</u><br><br>**Background:** This was an update to the presentation to the COVID-19 response meeting on the 11th August 2020, by way of an updated application and additional supporting documents following previous points raised.<br><br>Guy's & St Thomas' NHS Foundation Trust (GSTT) are hosting the King's Health Partners (KHP) COVID Data Analytics & Modelling Group. The purpose of the group is to utilise electronic health records (EHRs) to identify patients tested for COVID-19, influenza or other respiratory pathogens from 1 October 2016, and describe the phenotyping, allowing tracking and comparison of disease progression, care and outcomes.<br><br>**IGARD Observations:** |

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| | IGARD members reiterated their previous comment that this was potentially a very worthwhile study into phenotyping, and noting that London and in particular GSTT were a focal point for COVID-19 patients during wave 1 of the pandemic, welcomed the approach.<br><br>IGARD members reiterated their previous comment that the applicant would be receiving GP data from the Lambeth Data Net (LDN) and suggested it should be clearly established the type of data the applicant was receiving from LDN and ensure the flow of data into the data warehouse was GDPR compliant, since the supporting documents state that the applicant will be linking pseudonymised data from LDN, but the LDN patient-facing transparency materials state that they only disseminate "anonymous" or "anonymised" data, which, by definition, cannot be linked.<br><br>IGARD noted that the applicant had provided a Terms of Reference (TOR) for the GSTT BRC Covid Data Analytics Research Data Warehouse governance board. Notwithstanding the fact that NHS Digital should undertake an exploration of the TOR to ensure consistency across all applicants with similar committees, IGARD members noted that the governance review appeared to be robust in establishing scientific rigor, however the TOR appeared to be missing key considerations including, but not limited to:<br><br>• general information governance principles,<br>• checking compliance with relevant Data Protection law<br>• demonstrating the COVID-19 purpose (to satisfy the COPI legal basis relied on) (When this legal basis falls away, replacing this with an assessment of the benefits to the health and social care system);<br>• aligning the TOR to the various supporting documents provided, including consideration of data minimisation.<br><br>IGARD members noted that the committee members appeared to be clinical staff, and suggested that someone with an IG background or from the Trust's Data Protection Officer office may be part of the committee (if the clinical staff did not have dual roles or Information Governance expertise). In addition, IGARD suggested earlier involvement of a lay member, since the applicant was relying on emergency legislation, which would appear to support the case for a lay member to be involved sooner rather than later.<br><br>IGARD members noted the update from NHS Digital with regard to the Data Controllers and Data Processors who may be involved in the application, however it should be made clear with regard to the involvement of all parties, and where acronyms of organisations were used that these were checked at all stages, since many of them were very similar. In addition, and noting that the King's Health Partners (KHP) COVID Data Analytics & Modelling Group may access this data via the "Rosalind platform", care should be taken to ensure the application clearly defined the data access, since the location of the Rosalind platform is unclear and may be outside the UK.<br><br>IGARD members noted within the Integrated Research Application System (IRAS) document, provided as part of the review, that opt outs would be applied, however since the applicant was relying on the Health Service (Control of Patient Information Regulations) 2002 (COPI), opt outs do not need to be applied. However, care should be taken since when the emergency legislation falls away, and should the applicant not have applied opt outs, an amendment IRAS form would need to be submitted to note that opt outs had **not** been applied. |

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| | IGARD members noted the abridged Data Protection Impact Assessment (DPIA) provided as a supporting document. This abridged DPIA stated that "*none of the data constitutes 'patient confidential data' nor 'personal data', nor 'patient identifiable data*'" which appeared to be factually incorrect on the supporting documents provided (as pseudonymised data is personal data under GDPR). IGARD suggested that the applicant reconsider this assessment and complete a full DPIA. |
| **3.3** | <u>UK Biobank / Nuffield Department of Population Health Group (no NIC number available)</u><br><br>**Background:** This was an amendment to an application already approved for a consented cohort of patients for the addition of GPES Data for Pandemic Planning & Research (GDPPR).<br><br>NHS Digital noted that this amendment application would need to be reviewed by the Profession Advisory Group (PAG) and IGARD business as usual (BAU) Thursday meeting for recommendation.<br><br>The following observations are made on the basis of the verbal briefing only.<br><br>**IGARD Observations:**<br><br>Noting that the applicant would be using consent as their legal basis, IGARD members suggested that NHS Digital explore with the information governance (IG) directorate whether the Health Service (Control of Patient Information Regulations) 2002 (COPI) would be a more pragmatic legal basis for the GDPPR data, aligning the legal basis for processing, with the time frame for the GDPPR dataset.<br><br>IGARD members noted the verbal update from NHS Digital and looked forward to receiving the application in due course to both a COVID-19 response meeting and IGARD BAU meeting. |
| **3.4** | <u>NIC-390154-Z4M0F Public Health England (PHE)</u><br><br>**Background:** This was a verbal update to verbal presentation to the COVID-19 response meeting on the 7th and 28th July 2020. This was a new application for GPES Data for Pandemic Planning & Research (GDPPR) and is a priority request with a legal basis of the Health Service (Control of Patient Information Regulations) 2002 (COPI).<br><br>The broad aim is understanding COVID-19 and risks to public health, trends in COVID-19 and such risks, and controlling and preventing the spread of COVID-19 and such risks, for research and planning purposes.<br><br>NHS Digital noted that a draft application and supporting documents were available, but had not been provided for review since the application was in the process of being extensively updated by the applicant, following previously received feedback from both IGARD and NHS Digital's information governance (IG) directorate.<br><br>The following observations are made on the basis of the verbal briefing only.<br><br>I**GARD Observations:**<br><br>IGARD members noted the verbal update from NHS Digital and looked forward to receiving the application in due course to both a COVID-19 response meeting and / or IGARD business as usual (BAU) meeting. |
| **3.5** | <u>NIC-394372-G2W3W Department of Health</u> |

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| | **Background:** This was an urgent COVID-19 application from the Department of Health & Social care for the national medical examiner review of COVID-19 related deaths of health and social care staff in England.<br><br>NHS Digital noted that this had been through NHS Digital's prioritisation front door but that an urgent request had been submitted by the information governance (IG) directorate that a Data Sharing Agreement (DSA) be put in place, by way of a DARS application.<br><br>The following observations are made on the basis of the verbal briefing only.<br><br>**IGARD observations:**<br><br>IGARD members noted the verbal update from NHS Digital on this particularly complex but urgently needed review of COVID-19 related deaths of health and social care staff in England, and looked forward to receiving the application at a future COVID-19 response meeting and that due to the urgency of the request, that the application would be approved under the DARS SIRO precedent. |
| **4.** | <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. |