Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 24 September 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
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)
Louise Dunn	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS) (Observer: items 2.1 – 2.3)
Richard Hatton	Clinical Informatics (Observer: 2.1 – 2.3)
Emma Russell	Data Access Request Service (DARS) (Observer: item 2.1)
Karen Myers	IGARD Secretariat
Tracy Taylor	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Tom Wright	Data Access Request Service (DARS)

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

	Nicola Fear noted that members of her team at King's College London were recipients of Biobank data, but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 17th September 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	<u>The University of Manchester: ISARIC4C Coronavirus Clinical Information Network (CO-CIN) GPES record linkage (Presenter: Kimberley Watson / Garry Coleman) NIC-402963-P0Y5D</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), COVID-19 Second Generation Surveillance System, Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), Civil Registration data, National Diabetes Audit, Secondary Uses Service (SUS), COVID-19 Hospitalization in England Surveillance System, Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (GDPPR) and NHS 111 Online Dataset. The purpose is to answer research questions directed by the Scientific Advisory Group for Emergencies (SAGE) and enable The Coronavirus Clinical Information Network (CO-CIN) to report early and accurate findings to SAGE. CO-CIN informs the Department of Health and Social Care on a weekly basis about the clinical evaluation of disease in the United Kingdom, this information is essential to help health service planning and provision and rapid evaluation of interventions. NHS Digital advised that although the application stated that the University of Manchester was listed as the 'applicant', this was incorrect and that the application would be updated to correctly reflect the University of Oxford as the applicant. NHS Digital confirmed that one of the Co-Investigators was based at the University of Manchester, however, they were content that they would **not** have access to any of the NHS Digital data, and were therefore the university was not a Data Controller or a Data Processor. NHS Digital advised IGARD that following the discussion at the IGARD – NHS Digital COVID-19 Response meeting on the 22nd September 2020; the applicant had confirmed that the Principal Investigator of the study was a substantive employee of the University of Liverpool, however had an honorary contract with the University of Oxford for the purpose of the study, and therefore the University of Oxford was the sole Data Controller. NHS Digital also confirmed that they were in the process of reviewing the honorary contract to ensure the appropriate contractual arrangements. NHS Digital advised that the University of Liverpool and the University of Oxford had sought advice from their relevant legal teams, and were content that the data controllership arrangements outlined within the application were correct. NHS Digital also confirmed that they had liaised with NHS Digital's Information Governance (IG), to seek advice on the Scottish based Data Processors, and had received confirmation that there were no issues with this in terms of the legal basis (Health Service Control of Patient Information (COPI) Regulations 2002).

	Discussion: IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on 22nd September 2020. IGARD noted the update from NHS Digital in respect of the roles of the University of Liverpool, the University of Manchester and the University of Oxford, and the contractual arrangements for the Principal Investigator; and supported the confirmation that the University of Oxford was the sole Data Controller, and the work being undertaken by NHS Digital in reviewing the honorary contract to ensure the appropriate contractual arrangements were in place. IGARD noted the clarification that the University of Manchester were not a Data Controller or a Data Processor, and supported the update to the application to correctly state that the University of Oxford were the applicant. IGARD noted that NHS Digital had received confirmation from NHS Digital's Information Governance, in respect of there being no issues with the two Scottish Data Processors and the COPI legal basis being relied upon, and asked that NHS Digital uploaded the written confirmation from IG into NHS Digital's Customer Relationship Management (CRM) system. IGARD queried the funding arrangements for the study, noting that whilst the University of Liverpool were not a Data Controller or Data Processor, they were the recipients of the funding. NHS Digital advised that discussion had taken place on this issue, and they were content that whilst the University of Liverpool was in receipt of the funding, their legal team had reviewed the arrangements and confirmed that this would not impact the data controllership arrangements outlined. IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on 23rd September 2020. IGARD supported and endorsed the comments made by PAG, and in relation to the comments made, discussed whether the processing outlined could be achieved within NHS Digital's Trusted Research Environment (TRE), and asked that a suitable response was provided on this issue. IGARD also asked that section 5 (Purpose / Methods / Outputs) was amended, to ensure that it was written in plain English, and was in a style suitable for a lay reader; or to update to provide appropriate lay summaries throughout. In addition, IGARD asked that section 5 was updated to clarify that while the shielded patient list was not being shared, this data was available through the content of the GDPPR dataset. IGARD also agreed that further discussions around the use of the shielded patient list and the corresponding GDPPR data should be held with NHS Digital's Caldicott Guardian and Deputy Caldicott Guardian. **ACTION:** NHS Digital's Caldicott Guardian and Deputy Caldicott Guardian to further discuss with IGARD the Shielded Patient List being available via the GDPPR data set. IGARD also discussed whether the flow of data breached the Shielded Patient List Direction, or any other restrictions on the use of shielded patient data, and asked that written confirmation was provided from NHS Digital's IG. IGARD noted the outputs from the GP dataset would be shared with the Royal College of General Practitioners (RCGP) and the British Medical Association (BMA) concurrently, and asked that a plan was formulated addressing how this would be achieved. IGARD queried, in light of the volume of data being requested and the cost of the study, if there were any current or planned public engagements in terms of both the design and

	structure of the study, and the communications with the public in respect of the study outputs, and asked that section 5(c) (Specific Outputs Expected) was updated to address this. IGARD noted the statement in section 5(a) (Objective for Processing) that *"…consent was not required…"* in respect of the data collected for Tier 0, and asked that this was re-worded as this is debatable. In addition, IGARD asked that section 5(a) was updated to state tier 0 data was being collected under an ethically approved protocol. IGARD noted the references to 'comorbidity' and 'mortality', and asked that if this related to the issues being addressed relating to post-COVID-19, that this was made explicitly clear within section 1 (Abstract) and section 5; and that if relevant, the language used was reviewed, for example including terms familiar to the public such as 'long-COVID'. IGARD noted that the application appeared to suggest that SAGE would have access to the data, for example in section 5(a) that stated *"…SAGE members are able to access aggregated data…"*, and asked that the application was updated throughout to remove any suggestion that SAGE would have direct access to the data, as this was incorrect. IGARD queried if any other international collaborators were involved with the study, in light of specific references within the supporting documents provided, for example, the World Health Organization (WHO), and asked that section 1 and section 5 were updated to provide further details of this; and to confirm if they would have access to any data. IGARD noted that section 2(c) (Territory of Use) stated that the territory of use was both the UK and England and Wales, and asked that this was amended to remove the reference to England and Wales and to correctly state the UK. IGARD discussed the applicant's consent materials and NHS Digital advised that they were of the opinion that they were compatible. However, IGARD advised amendments were advisable in respect of any transition from COPI in the future, including, but not limited to references to anonymously linking data. IGARD queried the reference in section 5(a) that referred specifically to an aim regarding psychiatric sequelae, and suggested that in light of this the applicant may wish to consider requesting additional NHS Digital data to support this work, for example 'Mental Health Minimum Data Set' (MHMDS) and 'Improving Access to Psychological Therapies' (IAPT) data. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices; and supported the special condition that had been included in section 6 (Special Conditions) outlining specific action required by the applicant to have a compliant privacy notice by the end of October 2020. **Outcome:** recommendation to approve subject to the following conditions. 1. NHS Digital to provide a suitable response to PAG whether the processing outlined can be achieved with NHS Digital's TRE. 2. The applicant to formulate a plan addressing how the outputs from the GP dataset can be shared with the RCGP and the BMA at the same time. 3. To provide written confirmation from IG that the flow of data does not breach the SPL direction or any other restrictions on use of shielded patient data. The following amendments were requested: 1. In respect of the PAG points raised: a) To amend section 5 to ensure it is written in Plain English and in a style suitable for a lay reader (or to provide appropriate lay summaries throughout).

	b) To clarify within section 5 that while the shielded patient list is not being shared, these data are available through the content of the GDPPR dataset. 2. In respect of section 5(a): a) To reword reference to *"consent not required"*. b) To reflect that Tier 0 is being retrospectively and prospectively completed with identifying data relying on COPI. 3. To update section 1 and section 5 to make it explicitly clear if the issues being addressed relate to post-COVID-19 'comorbidity' and 'mortality', and if relevant, to review the language used, for example including terms familiar to the public such as 'long-COVID'. 4. To update the application throughout to remove any suggestion of SAGE having direct access to the data. 5. To update section 1 and section 5 to outline any international collaboration or consortium working, for example with 'WHO', and what (if any) access to the data they may have. 6. To amend section 2(c) to remove reference to *"England and Wales"*. 7. To update section 5(c) to address any current or planned public engagement in terms of the design and structure of the study and communications with the public regarding the outputs. The following advice was given: 1. IGARD suggested that in light of the psychiatric study aims noted within the application, the applicant may wish to consider requesting additional NHS Digital data to support this work, for example MHMDS and IAPT data. It was agreed the conditions would be approved out of committee (OOC) by IGARD Members.
2.2	<u>University of Exeter: A Spatial Microsimulation model of Comorbidity (Presenter: Dave Cronin) NIC-03716-R3W8Q</u> **Application:** This was an extension application for aggregated – Small Numbers not suppressed pseudonymised Hospital Episode Statistics (HES) data; and an amendment to the purpose of the analysis, to carry out further econometrical analysis of the impact of rurality and area level deprivation on hospital admissions for co-morbidity of Cardiovascular Disease (CVD), diabetes and obesity. The University of Exeter produced baseline small-area population estimates of co-morbidity outcomes (Cardiovascular Disease (CVD), diabetes and obesity) at the Lower Super Output Area (LSOA) level. These have been simulated for England using spatial microsimulation techniques to combine information from the Census of Population and the Health and Safety Executive (HSE) 2008-2010. The tabulated data is admissions for diabetes, CVD and obesity or any combination of these diseases (i.e. patient presenting with both diabetes and CVD disease) and were obtained at the LSOA level and were also broken down by age and gender at the LSOA level. However, on using the HES data for validation, clear spatial differences were noticed in expected rates of admission for the diseases of interest and the admissions reported by HES. By Mapping the rates of admission, it was clear that these differences were particularly apparent in rural areas and more deprived areas, where actual admissions were much lower than predicted admissions. **Discussion:** IGARD noted the information within the application that stated the NHS Digital data requested was **not** deemed to be 'personal' data, and discussed whether or not this was

	correct, noting the General Data Protection Regulation (GDPR) guidance on this, that the data could in fact be identified; and advised NHS Digital that it was their view that the data was anonymised data and not anonymous. IGARD therefore asked that the application was amended throughout to reflect that the data from NHS Digital **is** personal data. In addition, IGARD noted in section 4 (Privacy Notice) that a privacy notice was not required, due to the data not being personal data, and asked that in light of the discussion in relation to this issue that a special condition was inserted in section 6 (Special Conditions) , that within 1-month of signing the Data Sharing Agreement (DSA), the applicant would have published a GDPR compliant privacy notice. IGARD queried a number of publications cited in section 5(c) (Specific Outputs Expected), and noting that there seemed to be no reference to any NHS Digital data within these, asked that confirmation was provided if NHS Digital data had been used in the production of the publications; and if not, that the reference to the publications was removed from section 5(c) as this was not relevant. In addition, IGARD also asked that a special condition was inserted in section 6, stating that any forthcoming publications would cite NHS Digital as a source of the HES data. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the application throughout to reflect that the NHS Digital requested will be personal data. 2. To insert a special condition in section 6 that within 1 month of signing the DSA, the applicant will have published a GDPR compliant privacy notice. 3. In respect of the publications cited in section 5(c): a) To confirm if NHS Digital data was used in the production of the publications. b) If NHS Digital was not used, to remove the references to the publications. c) If NHS Digital data was used, to update to acknowledge the source(s) used for data. 4. To insert a special condition in section 6 that any forthcoming publications will cite NHS Digital as a source of the HES data.
2.3	<u>NHS England: Assuring Transformation (Presenter: Garry Coleman) NIC-389823-P1P6B</u> **Application:** This was a renewal application for identifiable and Aggregated –Small Numbers not Suppressed Assuring Transformation data; and an amendment to the sub-licensing terms for onward sharing. The purpose is to inform NHS England's monitoring of the progress in moving people with learning disabilities from inpatient to community settings. The data will 1) derive performance and quality indicators for Learning Disability services, in order to drive improvements in the services and to identify where good/poor practice is taking place; 2) allow NHSE to monitor and manage delivery of Transforming Care improvements to care for inpatients with a learning disability, behaviour which challenges or an autism spectrum disorder; 3) plan and deliver transformational change, reducing the reliance on inpatient care for people with learning disability, autism or both. **Discussion:** IGARD noted that this was an historical application and advised NHS Digital that the language used within the application was outdated and not in line with the language recommended by NHS England itself; and asked that the application was updated throughout, to ensure this reflected the latest guidance in respect of the language used and in making this

	accessible. In addition, IGARD offered support out of committee in reviewing the updated application, to ensure this aligns with the latest guidance. IGARD queried the information in section 1 (Abstract) in respect of the function of the s251 support from Health Research Authority Confidentiality Advisory Group (HRA CAG) and the direction under the Health and Social Care Act 2012, and asked that this was updated to reflect the interplay. IGARD noted the statement in section 3(c) (Patient Objections) that stated "*The flow of Assuring Transformation from NHS Digital to NHS England is exempt from Type 2 Objections…"*, and asked that this was updated to reflect that the **National Data Opt-out** will not apply, however the separate Assuring Transformation opt-out would apply. IGARD noted the events at Winterbourne View Hospital in 2011 and how this related to the work outlined within the application, and asked that section 5(a) (Objective for Processing) was updated to specifically reference these historical events, the role of the families involved in campaigning for change, and how this related to the application. IGARD queried the benefits outlined in section 5(d) (Benefits), in particular the reference to reducing *"…the reliance on inpatient care and to manage the safe discharge of current inpatients to the community."*, and queried that whilst this may be viewed as a benefit, this may not be appropriate for all individuals; and asked that the yielded benefits were updated to include (but not limited to) the patient experience. IGARD also suggested that the applicant should consider reviewing all the outputs and stated benefits, and whether additional patient based-outcomes could be included. Such review should include (but not be limited to) sensitivity around a reduction of in-patient numbers and the potentially negative impact this might have on patients. **Outcome:** recommendation to approve The following amendments were requested: 1. To update the application throughout to ensure this reflects the latest guidance from NHS England in respect of the language used and making this accessible. 2. To update section 1 to reflect the interplay between the HRA CAG support and the direction under the Health and Social Care Act. 3. To update section 5(a) with reference to the historical events at Winterbourne View Hospital and how this relates to the application. 4. To update the yielded benefits in section 5(d) to include (but not limited to) the patient experience. 5. To update section 3(c) to reflect that the National Data Opt-out policy will not apply, however the separate rights to opt out of Assuring Transformation will be applied. The following advice was given: 1. IGARD suggested that the applicant should consider reviewing all the outputs and stated benefits, and whether additional patient based-outcomes could be included. Such review should include (but not be limited to) sensitivity around a reduction of in-patient numbers and the potentially negative impact this might have on patients.
2.4	Barts Health NHS Trust: The impact of COVID-19 on surgical care and outcomes in England (COVID-19 Surgical Observatory) (Presenter: Louise Dunn) NIC-375669-J7M7F

	Application: This was a new application for access to pseudonymised Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) within NHS Digital's Data Access Environment (DAE). The purpose is to determine the disruption caused to NHS procedures during the period of the COVID-19 pandemic, to map how procedures are re-starting and to determine the potential impact of future waves of COVID-19 on services; and to inform policy makers at a local and national level about the ongoing need for care, to support future care provision and to plan for subsequent waves should they emerge. NHS Digital advised IGARD that the security dates for the Queen Mary University of London in section 1(c) (Data Processor(s)) had not been added, and that the application would be updated to reflect the correct dates. NHS Digital confirmed that the application had been updated to provide further information on the relationship between the Queen Mary University of London and Barts Health NHS Trust, and that both organisations would be accessing and processing the data. NHS Digital also advised that the application had been updated to reflect that the data accessed in NHS Digital's TRE would be pseudonymised. **Discussion:** IGARD welcomed the unique application and noted the importance of the study. IGARD noted and supported the updates to the application as outlined by NHS Digital, in relation to the Queen Mary University of London security dates and the data access within NHS Digital's TRE being pseudonymised. IGARD noted the update from NHS Digital in respect of the relationship between the Queen Mary University of London and Barts Health NHS Trust and that they were both Data Processors, and supported the update to the application to reflect this. In addition, IGARD noted that the Data Controller named in section 1(b) (Data Controller(s)) was also named as a Data Processor in section 1(c), and asked that this was reviewed, noting it had been previously agreed with NHS Digital that they would only be listed in section 1(b). IGARD noted that section 5 (Purpose / Methods / Outputs) only referred to *"Data Processor"* and asked that this was updated to ensure reference(s) were updated to reflect that there were two, or otherwise specifically name the relevant Data Processor. IGARD queried the special condition in section 6 (Special Conditions) that stated the NHS Digital data received by Barts Health NHS Trust would not *"…be shared with any other third party or organisation…",* when the research is utilizing NHS Digital's Trusted Data Access Environment. IGARD noted the special condition in section 6 (Special Conditions) related to the privacy notice, and asked that this was updated to reflect NHS Digital's standard wording as reflected in other applications; and, in addition, also asked that this was updated to state that Barts Health NHS Trust should ensure a privacy notice was published on their own website. IGARD asked that the privacy notice was updated to clearly state that National Data Opt-outs were not applied to the pseudonymised data and that the NHS Digital data being processed was 'pseudonymised' and not non-identifying. In addition, IGARD asked that the privacy notice was aligned with the data minimisation table in section 3(b) (Additional Data Access Requested) in respect of the start date of the data being accessed.

	IGARD also suggested that both data processors should have GDPR compliant privacy notices. IGARD noted that section 7 (Ethics Approval) stated ethical approval was not required but one of the supporting documents was a letter of HRA approval. IGARD asked for section 7 to be updated to reflect this. IGARD noted a number of acronyms in section 5 and 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 for technical jargon such as 'HRG' and 'ODS'. IGARD suggested the applicant may wish to consider the involvement of patients and the public at any early stage (for example in respect of refining study questions) and not just when results are ready for dissemination. In addition, IGARD suggested that the applicant may wish to engage with relevant stakeholder groups, for example CCGs, commissioners, NHS England and NHS Improvement, and to formulate a more structured output dissemination plan to ensure the maximum impact of this important research. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the Data Processors: a) To ensure that any Data Controllers listed in section 1(b) that are also Data Processors, are not also listed in section 1(c). b) To update the application throughout to reflect that QMUL is a joint Data Processor. c) To update section 5 to ensure reference(s) to the *"Data Processor"* are updated to reflect that there are two or otherwise specifically name the relevant Processor. 2. To update the special condition in relation to not sharing NHS Digital data with third party organisations. 3. In respect of the privacy notice: a) To update the privacy notice special condition in section 6 to reflect NHS Digital's standard wording as reflected in other applications. b) To add or update the special condition in section 6 to state that Barts Health NHS Trust should ensure a privacy notice is published on their own website. c) Relevant privacy notices to clearly state that National Data Opt-outs are not applied to the pseudonymised data. d) Relevant privacy notices to reflect that the NHS Digital data being processed is 'pseudonymised' and not non-identifying. e) To ensure consistency between the privacy notices and the data minimisation table in section 3(b) in respect of the start date of the data being accessed. 4. To update section 7 to reflect the HRA CAG approval received. 5. To amend section 5 to ensure that all acronyms upon first use be defined and further explained, such as '*HRG' and 'ODS'.* The following advice was given: 1. IGARD suggested the applicant may wish to consider the early involvement of patients and the public, specifically in respect of the study questions and the dissemination of outputs. 2. IGARD suggested that the applicant may wish to engage with relevant stakeholder groups, for example CCGs, commissioners, NHS England and NHS Improvement, and

	to formulate a more structured output dissemination plan to ensure the maximum impact of this important research.
2.5	<u>UK Biobank: R3 & R5 - MR1109 - UK Biobank (Presenter: Louise Dunn) NIC-08472-V9S6K</u> **Application:** This was an amendment application to add GPES Data for Pandemic Planning and Research (GDPPR) to the suite of products that they already receive from NHS Digital under this Data Sharing Agreement (DSA). The additional GDPPR data is required for the purpose to enable fuller case ascertainment of COVID-19. Coupled with the vast array of genetic and lifestyle information that UK BioBank has collected on all of its 500,000 participants, the primary care data will enable researchers to answer a wide range of research questions related to COVID-19, including why some people develop severe disease and others do not. The data will also enable researchers to, for example, better understand how underlying health conditions affect COVID-19 disease severity and to perform research into the longer-term health effects of COVID-19. The overall purpose of the research is to create a prospective epidemiological resource of 500,000 people aged 45-69 at the time of recruitment from around the UK. NHS Digital advised that the GDPPR data requested will replace any GP data currently held by the applicant. **Discussion:** IGARD noted the update from NHS Digital in relation to the GDPPR data replacing the GP data currently held by the applicant, and queried if the GP electronic medical record systems Egton Medical Information Systems (EMIS) and The Phoenix Partnership (TPP) data was still required for non-COVID-19 research, in light of the reference within the application to data being linked to primary care suppliers. IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on 1st September and 8th September 2020. IGARD noted that this application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) (see Appendix B) on 16th September 2020. IGARD supported and endorsed the comments made by PAG, and in relation to the comments made on point 1, discussed the consent materials and whether the materials supported the processing of medical records, and asked that NHS Digital collate a brief summary with all the relevant sections of the consent materials that would support the processing of the GDPPR data; and asked that this was uploaded NHS Digital's Customer Relationship Management (CRM) system. IGARD suggested that in relation to PAG point 2, clarification that the de-identified protocol published on line was current, the applicant may wish to consider reviewing and updating the De-identification Protocol as part of the current wider review of the document suite including the Material Transfer Agreement and in line with the General Data Protection Regulation (GDPR). IGARD asked that the applicant consider recent law case developments which may impact on Material Transfer Agreement arrangements. IGARD queried the data minimisation that had been applied to the data requested, and noted that similar applications that had requested the GDPPR data had been minimised by code set, and asked that in line with NHS Digital Data Sharing Standard 3, an analysis was provided of whether further data minimisation could be undertaken in respect of the code sets.

	IGARD noted the language used within section 5(a) (Objective for Processing) when referring to *"withdrawals"*, for example *"…fewer than 800 of the 500,000 participants have withdrawn from the study…"*, and asked that this was updated to ensure the language was more neutral. IGARD noted the statement in section 5(c) (Specific Outputs Expected) *"There is no restriction on the location of the researcher."* and asked that this was amended to state there is no contravtual restriction on the location of the researcher, however local laws may in practice prevent access. IGARD noted and commended the information within section 5(d) (Benefits) iii (Yielded Benefits) that stated the applicant had *"approved over 1,600 applications since it first opened to researches in 2012"*, and there had been *"over 1000 publications from researchers using the UK Biobank resources"*, and that web links had been attached for further information, IGARD asked that this should be updated further to include a high-level summary of key examples accruing to the health and care system. In addition, IGARD also asked that the benefits outlined in section 5(d) (iii) complied with NHS Digital's Expected Measurable Benefits Standard 5d. In addition, IGARD noted that on return, that a detailed analysis of the outputs and yielded benefits achieved should be provided, with highlights from the preceding period. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. **Outcome:** recommendation to approve subject to the following condition: 1. With reference to the PAG point 1: a) NHS Digital to collate a brief summary with the relevant sections of the consent materials that would support the processing of GDPPR data. b) To upload the summary on to NHS Digital's CRM system. The following amendments were requested: 1. In respect of data minimisation (NHS Digital Data Sharing Standard 3), to provide an analysis of what further data minimisation could be undertaken in respect of the code sets (and in line with other similar applications for GDPPR data). 2. To update section 5(a) to ensure the language when referring to *"withdrawals"* from the programme is more neutral. 3. To provide confirmation in section 1 and section if the applicant is still requiring EMIS and TPP data for **non**-COVID-19 research. 4. To clarify in section 5(c) that this DSA places no restriction on the geographical location of the researchers but any sharing must meet GDPR requirements. 5. In respect of the yielded benefits: a) To update section 5(d) (iii) to include a high-level summary of key examples accruing to the health and care system. b) To ensure the benefits outlined in section 5(d) (iii) comply with NHS Digital's Expected Measurable Benefits Standard 5d. The following advice was given: 1. IGARD suggested that in relation to PAG point 2, the applicant may wish to consider reviewing and updating the De-identification Protocol as part of the current wider review of the document suite (including the Material Transfer Agreement). 2. IGARD noted that on return that a detailed analysis of the outputs and yielded benefits achieved should be provided.

	3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. It was agreed the conditions would be approved out of committee (OOC) by IGARD Members.
3	Returning Applications 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	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and 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. The ratified action notes from Tuesday 22nd September 2020 can be found attached to these minutes as Appendix C.
4.1	Clinical Registries Annexe - The Sentinel Stroke National Audit Programme (SSNAP) SSNAP is a major national healthcare quality improvement programme based in the School of Population Health and Environmental Studies at King's College London. SSNAP measures the quality and organisation of stroke care in the NHS and is the single source of stroke data in England, Wales, and Northern Ireland. Following a discussion at the IGARD – NHS Digital COVID-19 Response Meeting on the 22nd September 2020, it was agreed with IGARD that NHS Digital would present the updated Sentinel Stroke National Audit Programme (SSNAP) version of the annexe. IGARD thanked NHS Digital for their efforts in working with NHS England both updating this annexe framework and completing it in respect of SSNAP in such a short time frame. IGARD members welcomed and supported the update from NHS Digital with regard to the minor outstanding issues.
5	AOB: There was no further business raised, the Deputy IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.
6	IGARD and Profession Advisory Group (PAG) Following conclusion of the IGARD business as usual section of the meeting, IGARD welcomed members of the PAG to the meeting. This was an opportunity for members to meet and to reflect on how things are working for both Groups, how processes can be streamlined and future plans. IGARD made the offer to PAG members to attend a future IGARD meeting to observe how the meetings and discussions are managed when reviewing applications, particularly those applications that have been via PAG.

	The NHS Digital's Caldicott Guardian agreed to share further suggestions as to how both IGARD and PAG can work together going forward in a more efficient and streamlined way. IGARD thanked PAG members for attending the meeting, and advised that they looked forward to working together going forward.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 18/09/20

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-397618-T8L8Z	NHS England (QH)	20/08/2020	1. In respect of the data flows and section 5 a. To provide a clear narrative of the data flows, data access and data location at all stages under this application; b. To clearly outline where the data is flowing from and to; c. To align the application and supporting documentation to remove any contradictory text in relation to the data flows.	IGARD members	Quorum of IGARD members	N/A
NIC-173508-F4X6P	Isle of Man Department of Health & Social Care (DHSC)	13/08/2020	1. In respect of NHS Digital's IG advice: a) To provide a clear justification of the DSA End Date of the 31st January 2021. b) To provide a copy of NHS Digital's IG advice which supports the timeline set out in the application. c) To ensure that the IG advice is uploaded to NHS Digital's CRM system.	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, 23rd September 2020

Application: **DARS-NIC-402963 ISARIC4C Coronavirus Clinical Information Network (COCIN) GPES record linkage** **Organisation name: NHS Digital** **Profession Advisory Group Agenda item: 2**
PAG requested NHS Digital to work with the applicant to clarify the data flows and the roles of the organisations involved. PAG discussed references to the Shielded Patient List in the use cases and shielding within the application. PAG recommends that this is clarified given that the application is not sharing the Shielded Patient List (but details on whether an individual is Shielded within the GDPPR dataset) PAG noted the data being provided as an extract albeit to a TRE in Scotland. Given the quantity of the data requested from NHS Digital being linked to one data set in COCIN, the proportionality of the movement of data was questioned: can the COCIN patient data be sent to NHS Digital TRE for linkage and research study? PAG supported the aims of this study. PAG stated that any outputs created from the GP dataset should be shared with the BMA / RCGP at the same time as others.

Attendees	**Role**	**Organisation**
Peter Short	Chair, Clinical Lead GP Data for Planning and Research	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	Senior Clinical Advisor	RCGP
Helen Buckels	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 16th September 2020

Application: **UK Biobank DARS-NIC-08472-V9S6K** **Organisation name: NHS Digital** **Profession Advisory Group Agenda item: 2**
PAG requested that DARS confirms all relevant consent materials support the processing of medical records and that for the 500,000 patients they have all agreed. PAG requests clarification that the de-identified protocol published on line https://www.ukbiobank.ac.uk/wp-content/uploads/2013/10/ukbiobank-summary-de-identification-protocol.pdf is current. PAG noted point 5.4.2 and that Biobank does not support a TRE; GP data is potentially distributed nationally and internationally. PAG support the application.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Helen Buckels	Secretariat	NHS Digital
Liz Gaffney	Head of Data Access	NHS Digital
Dave Roberts	Head of Business and Operational Delivery	NHS Digital
Peter Short	Directorate Lead	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, 22nd September 2020

In attendance (IGARD Members):	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (Specialist GP Member)
	Dr. Geoff Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Louise Dunn (Items 3.3 and 3.4)
	Karen Myers (IGARD Secretariat)
	Andy Rees (Item 3.7)
	Emma Russell (Observer: Item 3.1)
	Courtney Stephenson (Observer: 3.7)
	Kimberley Watson (Items 3.1 and 3.2)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD 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. **Declaration of interests:** There were no declarations of interest.
2	<u>IBM update</u> IBM is working with NHS Digital on improvements to the customer experience and related projects. The weekly update to the COVID-19 response meeting was provided via email subsequent to the meeting.
3.1	<u>NIC-402963-P0Y5D The University of Manchester</u> **Background:** This was a new application for pseudonymised Hospital Episode Statistics (HES), COVID-19 Second Generation Surveillance System, Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), Civil Registration, National Diabetes Audit, Secondary Uses Service, Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (COVID-19) and NHS 111 Online Dataset. The purpose of the application is to answer research questions directed by the Scientific Advisory Group for Emergencies (SAGE) and enable The Coronavirus Clinical Information Network (CO-CIN) to report early and accurate findings to SAGE.

	NHS Digital noted that this was an urgent application that would be considered by the Profession Advisory Group (PAG) on Wednesday 23rd September and would be presented to the IGARD business as usual (BAU) meeting on Thursday, 24th September 2020. **IGARD Observations:** IGARD members noted that the application was to be presented to the IGARD BAU Meeting on Thursday, 24th September 2020, following a review by the Profession Advisory Group (PAG) on Wednesday, 23rd September, with an extract of the PAG minutes appended to IGARD's published minutes. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for the update. A number of observations were made which NHS Digital may wish to consider before the application is presented to both PAG and IGARD, and these observations by IGARD members are based on the verbal briefing only, including, but not limited to: • Amend the application title to reflect that the applicant is the University of Oxford. • Clarification of which University will be co-signing the honorary contract in respect of the Principal Investigator (and to load a copy of the appropriate contract to CRM). • To ensure the appropriate NHS Digital Information Governance directorate written advice for the collection and dissemination of the data under this application, and that a copy be uploaded to NHS Digital's customer relationship management (CRM) system as a future supporting document. • Ensure NHS Digital's Information Governance are aware that the application notes Scottish based Data Processors, and clarify that there are no issues with this in light of the COPI legal basis being relied upon. • Include Northern Ireland to the application if required, or if not, to ensure that the appropriate terminology is used when referring to the UK / Great Britain. • Insert a special condition placing an obligation on the Data Controller to ensure that they have appropriate contractual arrangements in place with the Data Processor(s) which satisfies section 7 of COPI. • Ensure that the GDPPR data requested is minimised by both the code set and the cohort and update section 3(b) to reflect this. • Ensure the applicant is made aware the protocol and other supporting document refers to *"anonymised data"* and would suggest this is amended to reflect the data is *"pseudonymised"*; and in to ensure that there are no references to this in public facing materials. • Clarification as to why there was not a consent model for the tier 0 collection.
3.2	<u>NIC-NIC-400600-D8Z2W The University of Manchester</u> **Background:** This was a new application for an extract of GPES Data for Pandemic Planning and Research (COVID-19) for the Diabetes My Way - NHS Test Bed Programme, which is a digital intervention offered to individuals with Type 2 diabetes to help with self-support through the COVID-19 pandemic. NHS Digital advised that this application was still in draft format, and there were a number of outstanding queries that would need discussing with the applicant, including (but not limited to) if the work outlined extended beyond the COVID-19 pandemic, the cohort group and control group numbers stated, identifying the Data Controller(s) and Data Processor(s) and any commercial aspects.

	Observations: IGARD members welcomed and supported the update from NHS Digital with regard to the outstanding issues still to be confirmed with the applicant. IGARD noted that the research outlined was planned prior to the COVID-19 pandemic, and asked that clarification was provided as to what has changed during the pandemic compared to the initial research questions asked, and what the purpose is of having access to the additional NHS data requested. In addition, IGARD also asked what had changed in order to rely on The Health Service Control of Patient Information (COPI) Regulations 2002 legal basis, if this is the appropriate basis to rely on, and how they will facilitate a national rollout. IGARD noted the update from NHS Digital in relation to confirming the relatively small cohort group and significantly larger control group numbers (seemingly out of step with the usual cohort:control ratio), and supported the ongoing work of NHS Digital with the applicant to determine the purpose of using the figures stated. IGARD also advised that this application should be considered by the Profession Advisory Group (PAG) on and presented to a future IGARD business as usual meeting. IGARD noted that the applicant had stated that the NHS Digital data would not be used after the COVID-19 pandemic and suggested that this was re-considered in light of the potential benefits to the wider health and care system beyond this time limitation stated (with a transition to a suitable post-pandemic legal basis). IGARD also noted that NHS Digital was making enquiries about any potential commercial link or support for the research. Such a connection may be beneficial in advancing the programme, but the details would need to be set out within the application for transparency.
3.3	<u>NIC-394372 Department of Health and Social Care</u> **Background:** this was an update to the updates at the COVID-19 response meeting on the 25th August and the 1st September 2020. This was a new application from the DHSC requesting data for the National Medical Examiner Review of COVID-19 related deaths of health and social care staff in England. The Office for National Statistics (ONS) will do the work to identify the relevant deaths of care workers and will create a cohort of people to share with NHS Digital who will then link to LEDR-ID's of the identified deaths with NHS Number and existing civil registration data collected and share back to DHSC to enable the appropriate regional Medical Examiner to be notified and to accurately identify the deceased. NHS Digital advised that following the last review of this application on the 1st September 2020, a number of updates and amendments had been made to the application. **Observations:** IGARD members welcomed the update from NHS Digital with regard to the additional updates that had been made to the application following the last review on the 1st September 2020, and confirmed that they were supportive of the changes made and would also support this going via the SIRO approval route. IGARD noted the plans to publish a report at the end of the process, however queried if the applicant had any future plans to engage with the NHS and social care as a whole in terms of the publishing / sharing the outputs, and strongly suggested that a communications plan was

	produced that reaches the wider spectrum of interested parties and stakeholder, including (but not limited to) Unions, other professional bodies, bereaved families etc. IGARD noted the references within the application to *"certifying GP"* and suggested that this was amended to *"certifying professional"* to allow for a potential wider group of certifying professionals in future.
3.4	<u>NIC-396119-C8W3W University of Oxford</u> **Background:** This is a new application from Royal College of General Practitioners (RCGP), Public Health England and University of Surrey for Mental Health Services Data Set (MHSDS), Secondary Uses Service (SUS), Emergency Care Data Set (ECDS), Diagnostic Imaging Dataset (DIDs) and Cancer Registration Data. The purpose is to permit access to linked data already stored in the RCGP Research Surveillance Centre (RSC) for participants who have provided individual patient consent for use of their data as part of RAPID COMMUNITY POINT-OF-CARE TESTING FOR COVID-19 (RAPTOR-C19). The aim of RAPTOR-C19 to assess the diagnostic accuracy of multiple current and emerging point-of-care tests (POCTs) for active or past COVID-19 infection in the community setting. NHS Digital advised that this application was still in draft format, and there were a number of outstanding queries that would need discussing with the applicant, including (but not limited to) data minimisation and identifying the Data Controller(s) and Data Processor(s). **Observations:** IGARD welcomed this application and noted the importance and potential impact of the study. IGARD members welcomed and supported the update from NHS Digital with regard to the outstanding issues still to be confirmed with the applicant. IGARD noted that there was no reference within the application in respect of any linkage that would take place with other datasets and that identifiable data would be shared with NHS Digital, and suggested that the application was updated to reflect this. Noting the potentially critical importance of the study outlined, IGARD suggested that the applicant provide NHS Digital with any outstanding information in order to complete the DARS process. IGARD would welcome this application at the IGARD – NHS Digital COVID-19 Response Meeting on the 29th September and the IGARD BAU Meeting on Thursday 1st October 2020.
3.5	<u>NIC-373132-D3Y7P Nuffield Department of Primary Health Sciences</u> **Background:** This is a new application from Royal College of General Practitioners (RCGP), Public Health England and University of Surrey for Mental Health Services Data Set (MHSDS), Secondary Uses Service (SUS), Emergency Care Data Set (ECDS), Diagnostic Imaging Dataset (DIDs) and Cancer Registration Data. The purpose is to permit access to linked data already stored in the RCGP Research Surveillance Centre (RSC) for participants who have provided individual patient consent for use of their data as part of the Platform Randomised trial of INterventions against COVID-19 In older peoPLE (PRINCIPLE) trial.

	The aim is to be the national Primary Care platform trial for UK COVID-19, assessing the effectiveness of trial treatments in reducing the need for hospital admission or death for patients with suspected COVID-19 infection aged ≥50 years with serious comorbidity, and aged ≥65 with or without comorbidity, and during time of prevalent COVID-19 infections in the context of current care delivery. NHS Digital advised that this application was still in draft format, and there were a number of outstanding queries that would need discussing with the applicant, including (but not limited to) data minimisation and identifying the Data Controller(s) and Data Processor(s). **Observations:** IGARD welcomed this application and noted the importance of the study, and advised that it was rare to see a community-based trial. IGARD members welcomed and supported the update from NHS Digital with regard to the outstanding issues still to be confirmed with the applicant. IGARD noted that the data flow diagram provided appeared to refer to historical information, and were advised by NHS Digital that this would need updating to reflect any new information as agreed with the applicant.
3.6	<u>Clinical Registries Annexe - The Sentinel Stroke National Audit Programme (SSNAP)</u> **Background:** Following a discussion at the IGARD BAU meeting 17th September 2020, it was agreed with IGARD that NHS Digital would submit the Sentinel Stroke National Audit Programme (SSNAP) for review. SSNAP is a major national healthcare quality improvement programme based in the School of Population Health and Environmental Studies at King's College London. SSNAP measures the quality and organisation of stroke care in the NHS and is the single source of stroke data in England, Wales, and Northern Ireland. NHS Digital advised that the annexe had been updated to reflect a number of changes, including (but not limited to) adding King's College London and Netsolving Limited as Data Processors and adding the correct legislative reference in respect of justifying the public task legal basis. In addition, NHS Digital also advised that they have received the latest HRA CAG approval letter confirming support. **Observations:** IGARD thanked NHS Digital for their efforts in working with NHS England both updating this annexe framework and completing it in respect of SSNAP in such a short time frame. IGARD members welcomed and supported the update from NHS Digital with regard to the minor outstanding issues still to be confirmed with the applicant. IGARD noted the link to the programme-specific privacy notice, and suggested that it would be good practice to also publish this on the Data Controllers' websites for transparency and compliance with the requirements of GDPR. IGARD and NHS Digital agreed that an updated version of the annexe would be submitted to the IGARD BAU meeting on Thursday 24th September 2020; IGARD advised that as part of

	this review, they would expect to have a copy of the HRA CAG approval latter as a supporting document.
3.7	**<u>Recovery Trials Communication</u>** **Background:** The RECOVERY trial, coordinated by Oxford University, is a national clinical trial aimed at identifying treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19. The RECOVERY trial team will seek feedback from the existing Nuffield Department of Population Health and NHS DigiTrials public panels to ensure that the communications are appropriate to lay audiences, prior to review by the research ethics committee. These panels have already been involved in reviewing other RECOVERY-related materials. The RECOVERY trial team are looking to send a series of updates to participants to make them aware of the trial results to which they have contributed. IGARD were asked to review the proposed process for these communications. NHS Digital advised that communications from the trial would be aimed at two separate groups, which were grouped into 'children' and 'majority', and confirmed that they would not be communicating with the families of deceased individuals. NHS Digital also advised that the applicant was engaging with the relevant Ethics Committee and that ethics approval was in progress, and that the DigiTrials Patient Panel would be engaged from a patient perspective. **Observations:** IGARD welcomed the briefing and noted the importance of the proposed cohort communication work outlined. IGARD discussed the pros and cons of a separate DSA for this work, and advised that they were content with this, however suggested that links are made to the overarching DSA in section 1 of the additional DSA and the overarching DSA be provided as a supporting document for ease of reference. IGARD noted that NHS Digital would be acting as a Data Processor under GDPR, and advised that this would need reflecting in the application and the relevant privacy notices. IGARD also queried what the legal basis was for NHS Digital processing the data and were advised by NHS Digital that the legal basis would be the same as outlined in the overarching DSA. IGARD and NHS Digital discussed the legal gateway (consent) for the address details to be processed and the letter and its contents to be sent to cohort members. The consent materials and privacy notice were discussed in detail and the relevant sections relating to future contact with cohort members were identified. IGARD suggested that when this application is presented a brief note is included (e.g. as a supporting document) setting out how processing the address details and getting in contact with the cohort about all the various matters in the letter is compatible with the consent given by the cohort (the *"no surprises"* principle). IGARD noted that the ability for the cohort to withdraw their consent from the study was a key plank in the justification to be contacting the cohort and that any future iterations of the letters to participants must retain this text (including clear instructions on how to withdraw by phone, letter and email). IGARD queried how the risk was being minimised of bereaved families being contacted via the proposed communications, and if the most recent data was being used to reduce this risk, and

	were advised by NHS Digital that there was a two week delay between the creating the cohort and the mailshot being mailed out. While sadly this risk could not be eliminated entirely, IGARD agreed that appropriate steps were being taken to reduce this risk as much as possible.
4.	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.