Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 25 February 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member (item 1, 3.1 – 3.6 (discussion only), 6.1)
Prof. Nicola Fear	Specialist Academic Member (item 1, 2, 3.1 – 3.6)
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:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Nicola Bootland	Data Access Request Service (DARS)
Vicky Byrne-Watts	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: item 1 - 2.4)
Jonathan Hope	Data Access Request Service (DARS)
Dickie Langley	Privacy, Transparency and Ethics
Karen Myers	IGARD Secretariat
Charlotte Skinner	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

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 a professional link with Kings College London [NIC-384653-L3N2Q] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest. Imran Khan noted that he had directed eligible patients to the PRINCPLE trial through his work as an Out of Hours GP with Berkshire Healthcare NHS Foundation Trust. He also noted that he has had no further involvement with the clinical trial. It was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 18th February 2021 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	<u>Physical Health Checks for people with Severe Mental Illness (PHSMI) – Briefing Paper (Presenters: Nicola Bootland / Jonathan Hope)</u> The briefing paper was to inform IGARD that NHS England have directed NHS Digital to collect and analyse data in connection with PHSMI. To deliver the data required to monitor delivery of PHSMI, routinely recorded General Practice data will be extracted by NHS Digital via the General Practice Extraction Service (GPES) with an initial GPES extract containing historical information and thereafter an extract on a quarterly basis. The data will help monitor delivery of the full comprehensive health check and collect benchmarking information on the uptake of the corresponding relevant follow-up interventions and access to national cancer screening programmes. In 2016, the Five Year Forward View for Mental Health (MHFYFV) set out NHSE approach to reducing the stark levels of premature mortality for people living with severe mental illness (SMI) who die 15-20 years earlier than the rest of the population, largely due to preventable or treatable physical health problems. IGARD noted that this briefing paper had been reviewed by members out of committee, and comments had been shared (via the IGARD Secretariat) with the presenters on the 19th February 2021 but had requested a discussion with NHS Digital with regard to queries raised. IGARD welcomed the briefing paper and provided some verbal feedback to further support the out of committee comments made to NHS Digital, and advised that they looked forward to receiving an updated briefing paper alongside a first of type application.
3	**Data Applications**
3.1	<u>University of Oxford: PRINCIPLE: Platform Randomised trial of INterventions against COVID-19 In older peoPLE (Presenter: James Gray) NIC-411161-G4K7X-v2.5</u> **Application:** This was an amendment application to the existing Data Sharing Agreement (DSA), to request 28 day follow up data for Hospital Episodes Statistics Admitted Patient Care (HES APC), HES Critical Care, GP Data for Pandemic Planning & Research (GDPPR) data and Civil Registration (Death) data, for all members of their cohort on a monthly basis. The PRINCIPLE trial is the only national Urgent Public Health priority clinical trial evaluating potential therapeutics for COVID-19 in the primary care setting, endorsed by the four Chief

	Medical Officers. The trial aims to find out whether early treatment in the community speeds recovery and reduces the need for hospital admission for those with COVID-like-Illness. **Discussion:** IGARD noted that aspects of this application had last been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 9th February 2021. IGARD also noted that v1.2 of the application had been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 17th February 2021 (see Appendix B). IGARD noted and supported the comments made by PAG from the 17th February 2021. IGARD noted within section 1 (Abstract) that the Data Safety Committee reviewed the trial data *"weekly"*, and asked that this was amended to clarify that the study team were content with the **monthly** flow of NHS Digital data, and that this would suffice and meet the needs of the weekly updates outlined. IGARD noted that access to the Summary Care Records (SCR) was relying on the UK General Data Protection Regulation (GDPR) Article 9(2)(h), however asked that section 1 was updated in respect of Article 9, to expressly refer to Article 9(3) of UK GDPR and section 11(1) DPA 2018 and to clearly describe how the schedule conditions are met in order to establish a legal gateway for access to the SCR. IGARD queried the statement in section 3(c) (Patient Objections) that stated access to the SCR would be via consent, and noting that this was inconsistent with the rest of the application, asked that this information was updated to accurately and consistently state that access to the SCR would be via the Health Service Control of Patient Information (COPI) Regulations 2002. In addition, IGARD noted the statement in section 3(c) that there was a *"…**separate opt-out in place for SCR which will be applied**"*, and asked that this was updated to state that the opt-out *"…**has** been applied".* In addition, IGARD noted the Caldicott Guardian's assessment of the legal basis for access to SCR in supporting document 6, and suggested that the NHS Digital Data Access Request Service (DARS) Team, shared the Caldicott Guardian's opinion with NHS Digital's Privacy, Transparency and Ethics (PTE) (formerly Information Governance). IGARD asked that written confirmation be sought that PTE were content with the Caldicott Guardian's assessment; and that the written confirmation was uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD reiterated comments made at the IGARD – NHS Digital COVID-19 Response meeting on the 9th February 2021, that section 3(b) (Additional Data Access Requested) should be updated to clearly show how the GDPPR data had been minimised to code blocks / sets, and in line with NHS Digital's Data Minimisation Standard. IGARD queried whether the applicant would find the NHS Business Services Authority (NHS BSA) data more timely and complete to achieve their research goals outlined, instead of the GDPPR data requested, or as well as the GDPPR data requested. IGARD confirmed that they would be supportive of this flow of data should the applicant wish to apply for it via NHS Digital. In addition, and should the applicant apply for this data, that an appropriate justification for this dataset should be included in section 5 (Purpose / Methods / Outputs), as appropriate. IGARD queried the participant cohort numbers outlined in section 5(a) (Objective for Processing), and noting that these appeared to be outdated, asked that this was updated to correctly include **all** of the participant cohort numbers.

	IGARD also noted that section 5(a) contained historical dates relating to actions for the study, and asked that the dates were updated to reflect actions that have or have not taken place. IGARD queried the statement in section 5(b) (Processing Activities) that *"On a monthly basis the trial team will send the entire PRINCIPLE cohort to NHS Digital"*, and asked that this was reviewed and amended as necessary to accurately reflect what was actually happening, for example, that just the relevant data was being sent to NHS Digital. IGARD noted that section 5 referred to a supporting document, and asked that either this was removed from this public facing section of the application, as the supporting documents would not be available to view by the public, and was therefore not relevant; or that a publicly accessible link was provided. IGARD noted the language used within section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) to COVID-19 *"sufferers"*, and asked that these references were either amended or removed. IGARD suggested that in respect of transparency, the Department of Health and Social Care (DHSC) may wish to consider a more nuanced or layered approach for citizens to decline future communications rather than exercising the National Data Opt-out. IGARD also suggested that the transparency materials were reviewed and amended as necessary, to refer to the study's initial focus on **short term** follow up, which may be extended to a period of 10 years. IGARD advised that when this application comes up for renewal, extension or amendment, they would expect the outputs and benefits to be clearly outlined to reflect the work that has been undertaken in this ground-breaking research, and the benefits outlined should accrue to health and social care. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, to ensure that the benefits have been appropriately detailed and PTE endorsement of the SCR approach; and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend section 1 to make it clear that the study team are content that the monthly flow of data will suffice and meet the needs of their weekly updates. 2. To update section 1 as to how UK GDPR Article 9(3) is satisfied for SCR. 3. To update section 3(b) to clearly show how the GDPPR data has been minimised to code blocks / sets, in line with NHS Digital's Data Minimisation Standard. 4. To update section 3(c): a) To state that access to the SCR will be via COPI and not consent. b) To amend the second paragraph to note that the opt-out for the SCR *"has been applied".* 5. To update section 5(a): a) To include all of the participant cohort numbers. b) To ensure that historical dates are updated to reflect actions that have or have not taken place. 6. To update section 5 to remove the reference to any "*supporting documents*" or to provide a publicly accessible link.

	7. To review the reference in section 5(b) to the *"entire PRINCIPLE cohort"* being sent to NHS Digital and amend as necessary to reflect what is actually happening, for example, just the relevant data being sent to NHS Digital. 8. To amend or remove the references in section 5(c) and section 5(d) to COVID-19 *"sufferers"*. The following advice was given: 1. IGARD suggested that NHS Digital DARS Team share the Caldicott Guardian's assessment of the legal basis for access to SCR with NHS Digital's PTE; and seek written confirmation that PTE are content with the assessment and upload the written conformation to NHS Digital's CRM system. 2. In respect of transparency: a) IGARD suggested that, DHSC may wish to consider a more nuanced or layered approach for citizens to opt out of communications rather than exercising the National Data Opt-out. b) IGARD suggested that the transparency materials are reviewed and amended as necessary, to refer to the study's initial focus on **short term** follow up (which may be extended to a period of 10 years). 3. IGARD queried whether the applicant would find the NHSBSA data more timely and complete to achieve their research goals outlined - instead of the GDPPR data requested, or as well as the GDPPR data requested. IGARD would be supportive of this flow of data should the applicant wish to apply for it; and an appropriate justification for this additional data should be added in section 5. 4. IGARD advised that when this application comes up for renewal, extension or amendment, they would expect the outputs and benefits to be clearly outlined, and to reflect the work that has been undertaken in this ground-breaking research, and the benefits accrued to health and social care since the application was last seen. 5. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, to ensure that the benefits have been appropriately detailed and PTE endorsement of the SCR approach. 6. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
3.2	<u>Health Data Research UK (HDRUK): R14.2 - CVD-COVID-UK. Cardiovascular disease and COVID-19: using UKwide linked routine healthcare data to address the impact of cardiovascular disease on COVID-19 and the impact of COVID-19 on cardiovascular diseases. (Presenter: Catherine Day) NIC-381078-Y9C5K-v4.2</u> **Application:** This was an amendment application to the existing Data Sharing Agreement (DSA), to add the following datasets to the Cardiovascular Disease Trusted Research Environment (CVD TRE): 1) COVID-19 UK Non-hospital Antigen Testing Results (Pillar 2); 2) COVID-19 UK Non-hospital Antibody Testing Results (Pillar 3) data; 3) Vaccination event dataset; 4) Vaccine adverse reaction dataset. The British Heart Foundation (BHF) Data Science Centre, which is embedded within Health Data Research UK (HDR UK), is working in partnership with NHS Digital to establish a Cardiovascular Disease Trusted Research Environment (CVD TRE) [service] for England, to enable analyses of linked, nationally collated healthcare datasets. This project is entitled 'CVD COVID UK', and will enable timely research on the effects/impacts of cardiovascular disease on COVID-19, and the direct and indirect impacts of COVID-19 on cardiovascular diseases;

	coordinate similar approaches across the four nations of the UK; and future proof an enduring CVD TRE service post-COVID-19. **Discussion:** IGARD noted that aspects of this application had last been seen by the IGARD – NHS Digital COVID-19 Response meeting on the 19th January 2021. IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 24th June 2020, and that notes from this meeting had been attached to the IGARD minutes from the 23rd July 2020. IGARD noted that because the TRE was structured as a pseudonymised dataset, and that access was therefore granted on a pseudonymised basis to the TRE, that all of the appropriate steps must be taken to ensure that there was no identifying data present in the onboarding datasets, for example, by way of free text fields. IGARD therefore asked that confirmation was provided in section 5 (Purpose / Methods / Outputs), that the free text fields were **not** flowing as part of the vaccine adverse reaction dataset into the TRE. IGARD noted that following the last review of this application on the 3rd December 2020, where IGARD had recommended for approval with conditions, NHS Digital's Senior Information Risk Owner (SIRO) had taken the decision to approve the application. IGARD therefore reviewed the previous comments made, and agreed that most of the previous points had been addressed, however made the following comments in respect of the data controllership and the transparency materials: IGARD previously noted that the issue of data controllership had been discussed, and that a special condition had been inserted in section 6 (Special Conditions), that stated a joint data controllership agreement, as per Article 26 of the UK General Data Protection Regulation (GDPR) would be put in place and signed by all relevant Data Controllers within 2 months of signing the Data Sharing Agreement (DSA). IGARD asked that confirmation of the finalised data controllership agreement was provided; and that a copy of the agreement was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. In addition, IGARD acknowledged the improvements the applicant had made to the public facing transparency materials, however asked that they were updated further to ensure the essence of the data controllership agreement was communicated. IGARD also noted the information within the privacy notice in respect of the wider consortium members, however asked that this was also updated to reflect the current list of joint Data Controllers and to explain that they were a group with different responsibilities from the consortium members. IGARD also noted that the previous condition was in respect of the legal basis that was being relied up on for the collection, dissemination and use of the Sentinel Stroke National Audit Programme (SSNAP) data, and that NHS Digital has been directed by the Secretary of State for Health and Social Care, under section 254 of the Act to establish and operate a system for the collection and analysis of the information specified for this service for COVID-19 purposes only. IGARD advised NHS Digital that further thought / discussions should be held in terms of extending the Direction, for example, for non-COVID-19 purposes and other applicants. IGARD queried the references in section 5(a) (Objective for Processing) to *"future proofing"*, for example, in respect of post-Covid-19, and asked that, noting the application relies upon COPI, that this was either updated to remove the references, or that further details were provided.

	IGARD noted within section 5(b) (Processing Activities) that there was ongoing discussion in respect of data minimisation in the TRE, and asked that this was updated accordingly to reflect the outcome from those discussions. IGARD asked that the CVD-COVID-UK Oversight Committee minutes from the 2nd February 2021, were provided as a supporting document, as part of the next iteration of this application; and that a copy of the Committee minutes were uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD would expect on renewal, extension or amendment, that the yielded benefits would be updated to reflect the high profile and high impact work carried out, in light of the urgency under which the data flowed in 2020, via the expedient SIRO Precedent; noting the previous comments made by the applicant that benefits would emerge within weeks of receipt of the data. IGARD asked that if there were delays to the receipt or processing of the data or other factors, these could instead be highlighted in the yielded benefits section. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, to review the yielded benefits, to review the Committee minutes, and how the data controllership agreement was progressing. **Outcome:** recommendation to approve subject to the following condition(s) 1. To provide confirmation in section 5, that the free text fields are **not** flowing as part of the vaccine adverse reaction dataset flowing to the TRE. The following amendments were requested: 1. In respect of the data controllership / agreement: a) To provide confirmation of the finalised data controllership agreement. b) To ensure the finalised data controllership agreement is uploaded to NHS Digital's CRM system. c) To ensure the essence of the data controllership agreement is communicated in the public facing transparency materials. d) To update the privacy notice to reflect the current list of joint Data Controllers and explain that they are a group with different responsibilities from the wider consortium members. 2. To update section 5(a) to either remove or provide further details about the reference to *"future proofing"*. 3. To update section 5(b) to reflect the ongoing discussions in respect of the data minimisation in the TRE. The following advice was given: 1. In respect of the CVD-COVID-UK Oversight Committee: a) IGARD asked that the CVD-COVID-UK Oversight Committee minutes from the 2nd February 2021, were provided as a supporting document, as part of the next iteration of this application. b) To upload a copy of the Committee minutes to NHS Digital's CRM system. 2. IGARD would expect on renewal, extension or amendment, that the yielded benefits would be updated to reflect the high profile and high impact work carried out, in light of the urgency under which the data flowed in 2020, via the expedient SIRO Precedent; (noting the comment that benefits would emerge within weeks of receipt of the data). If there were delays to the receipt or processing of the data or other factors, these could instead be highlighted in the yielded benefits section.

	3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, to review the yielded benefits, to review the Committee minutes, and how the data controllership agreement is progressing. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
3.3	<u>University of Cambridge: Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) mental health record linkage with the NHS Hospital Episode Statistics and Mortality records (Presenter: Vicky Byrne-Watts) NIC-356234-W2K8R-v0.7</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES), Civil Registration (Deaths) data and Emergency Care Data Set (ECDS); for the purpose of creating a research resource to be used for research projects aiming to investigate physical health outcomes and receipt of health care in people with mental disorders attending secondary mental health care services provided by CPFT. The cohort for this project is individuals who received treatment from CPFT since 2005 and who have not notified CPFT that they wish to opt out of having their data collected and / or linked; and / or individuals who are or have been a resident with CPFT's geographical catchment area (Cambridgeshire and Peterborough) since 2005 and attended hospital for any reason whilst a resident in the catchment area. The cohort is approximately 1 million individuals (cases and controls combined). Relatively little is known about the health conditions underlying health inequalities, and the associations between physical and mental health, although this knowledge is clearly important in order to develop interventions to improve the situation. The over-arching objective of this research programme is to provide information that will assist in narrowing the mortality and physical morbidity disadvantage experienced by people with mental disorders. **Discussion:** IGARD welcomed the application and noted the importance of the study and the ground-breaking work outlined within the application. IGARD noted within the application that Cambridgeshire and Peterborough NHS Foundation Trust were the sole Data Controller, however queried the role of the University of Cambridge, in light of the information provided in supporting document 1, the study protocol, and supporting document 3.1, the Medical Research Council grant offer letter, dated the 13th February 2018, that referenced the University of Cambridge as being the applicant organisation and the recipient of the grant. IGARD asked that a written explanation was provided, in line with the UK General Data Protection Regulation (UK GDPR) and NHS Digital's Data Access Request Service (DARS) Standard on Data Controllers, as to why the University of Cambridge were **not** considered joint Data Controllers, particularly in light of the information provided in the supporting documents; or if the University of Cambridge were considered joint Data Controllers, to update the application throughout to reflect this. IGARD also noted the reference to *"Microsoft"* as having a role within the study, in supporting document 3.1, and queried if they were still involved; and were advised by NHS Digital that they were no longer involved. IGARD queried the references throughout the application to *"letters of access"*, *"honorary contracts"* and *"research passports"*, when referring to individuals substantively employed by organisations other than Cambridgeshire and Peterborough NHS Foundation Trust who wish to process the data, and were advised by NHS Digital that anyone accessing NHS Digital under one of those categories, would need to complete and sign an addendum that was provided by NHS Digital. IGARD noted the update from NHS Digital and asked that a special condition was inserted in section 6 (Special Conditions), stating that anyone accessing the

	data under an honorary contract, a letter of access or a research passport, may only do so once there was an appropriately completed and returned addendum to that contract, letter or passport, specifically relating to NHS Digital data, on the form provided by NHS Digital's DARS Team. IGARD noted the separate flows of data for the two cohorts, and that both flows of data had both Research Ethics Committee (REC) and s251 support, but queried if applying the National Data Opt-out (NDO) to both would enable the possible reidentification of those who had applied for the NDO; and asked that the applicant clarified whether or not they could use a different pseudonymiser to avoid inadvertently reidentifying those who had exercised the NDO. IGARD asked for confirmation whether it was appropriate to apply the NDO to those patients who had consented to be part of the research database. IGARD noted the references in section 5 (Purpose / Methods / Outputs), to specific academic papers, and asked that this public facing part of the application, was updated, to either include a fuller, searchable reference or to include a relevant web link. IGARD suggested that, noting the significant amount of citizens' data (over one million data subjects) that were involved in the research, that the applicant may wish to consider using wider communication with the local community to raise awareness, to highlight the clear potential benefits and also to highlight citizens' right to exercise the National Data Opt-out (NDO) if they did not want their data used in this way. IGARD advised that they would wish to review this application when it comes up for renewal, due to the significant amount of data flowing and the novel use of the data. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the data controllership: a) To provide a written explanation (in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers) why the University of Cambridge are **not** considered joint Data Controllers, particularly in light of the information provided in the supporting documents, for example the protocol. b) If the University of Cambridge are considered joint Data Controllers, to update the application throughout to reflect this. The following amendments were requested: 1. To insert a special condition in section 6 stating that anyone accessing the data under an honorary contract, a letter of access or a research passport, may only do so once there is an appropriately completed and returned addendum to that contract, letter or passport, specifically relating to NHS Digital data (in the form provided by NHS Digital's DARS Team). 2. The applicant to clarify whether or not they can use a different pseudonymiser to avoid inadvertently reidentifying those who have exercised the NDO. 3. To clarify if the database for re-identification for those patients providing consent will have the NDO applied. 4. To update the references to academic papers in section 5, to either include a fuller searchable reference or a relevant web link. The following advice was given: 1. IGARD suggested that noting the significant amount of citizens' data (over one million data subjects) involved in the research, that the applicant consider using wider communication with the local community to raise awareness, to highlight the clear

	potential benefits and also to highlight citizens' right to exercise the NDO if they do not want their data used in this way. 2. IGARD advised that they would wish to review this application when it comes up for renewal due to the significant amount of data flowing and the novel use of the data. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
3.4	<u>King's College London (KCL) and King's College London NHS Foundation Trust (KCL NHS FT): long term healthcare usage of Bariatiric / Metabolic surgery compared to commonly performed Elective General Surgery Procedures (Presenter: Vicky Byrne-Watts) NIC-384653-L3N2Q-v0.4</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) data; for the purpose of a study, comparing short and long-term safety outcomes and overall healthcare utilization among patients, who underwent bariatric surgery and other types of elective surgical interventions for diseases at King's College Hospital as part of a retrospective cohort review of patients from 7 different general surgery specialities (Adrenal, Antireflux, Bariatric, Gallbladder (inpatients & day surgery), Colorectal, Hernia, Neck surgery). The outcome of the study will draw attention to the safety of bariatric surgery. The surgery for the 100 bariatric patients took place between 2013 and 2015, this is compared to 700 other patients who had undergone 6 other procedures including laparoscopic cholecystectomy, colectomy, anti-reflux surgery, adrenalectomy, thyroidectomy and hernia surgery in the same hospital between 2006 and 2015. By analysing the healthcare usage patterns of the different surgical specialties and comparing it to bariatric surgery, conclusions can be drawn regarding the comparative safety of each operation. To accurately reflect this, a nationwide search needs to be made to capture all admissions and health visits of individual patients. This is the first study to date that compares the healthcare usage of different general surgery specialties. **Discussion:** IGARD noted the processing outlined in the application aligned with the section 251 support, but noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval letter dated the 7th April 2020, contained a condition of approval, in relation to the King's College London NHS Foundation Trust staff training for the Data Security and Protection Toolkit (DSPT); and asked that a special condition was inserted in section 6 (Special Conditions), replicating the condition of approval. IGARD also queried the special condition in section 6 that stated *"The Data Controller should ensure appropriate data processing agreements with all data processors contracted to undertaking work referenced within this agreement."*, and asked that this was removed as it was not necessary. IGARD noted that the data minimisation column in section 3(b) (Additional Data Access Requested) did not contain information relating to indicative cohort size, and asked that this was updated to include this information. IGARD noted that section 5 (Purpose / Methods / Outputs) contained some presumptuous statements, in terms of positive outcomes, for example, the reference to the assumption that the outcomes will show the safety of the surgery; and asked that section 5 was amended throughout to ensure there was no assumptions on positive outcomes, for example, by stating it would *"contribute to the understanding"* or similar. IGARD queried the information in section 5(a) (Objective for Processing) that the study team, *"…plans to look at longterm rate of re-admissions and related length of stay, emergency*

	department attendances and GP encounters over a period of 5-year The study team plans to look at longterm rate of re-admissions and related length of stay, emergency department attendances and GP encounters over a period of 5-year…", and asked that, in respect of the GP encounters, clarified where the GP data was being obtained from, noting that this would not be part of the data flow received from NHS Digital. In addition, IGARD asked that confirmation was provided if the GP data was being linked to the data requested in the application; and that if **no** GP data was being obtained for linkage at the moment, to either remove the reference to GP data, or update the application to state this may be sought in the future. IGARD noted a number of references in section 5, that may not be suitable for a lay reader, and asked that the use of language throughout was revised, including, but not limited to the references to *"discarding"* data, *"commissionaires"* and *"caretakers"*. In addition, IGARD also asked that section 5 was updated with a description of how the data was stored and accessed on campus / the hospital. IGARD noted the role of Ethicon Investigator Initiated (IIS) Study Committee as the funder of the study, and asked that for transparency, section 5(a) was updated to clarify that Ethicon were also involved with the manufacturing and sale of medical devices used in bariatric surgery. IGARD noted that there was a discrepancy between the quantum of funding provided by the private funder and the charges made by NHS Digital, and asked that further clarification was provided in section 11, of how any shortfall in funding vis-à-vis NHS Digital's charges is being met by the applicant. In addition, IGARD also asked that it was made explicitly clear that the Principal Investigator who was also a substantive employee of King's College Hospital NHS Foundation Trust, carrying out bariatric surgery in private practice. IGARD noted the references in section 5(c) (Specific Outputs Expected) to the study outlined being a *"long-term study"*, and asked that this was updated to clarify that it was in fact a *"medium term study"*. IGARD suggested that the applicant may wish to amend the application to reflect that a long-term study may be of use in the future. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, because as highlighted in the application, the study should be concluded within one year of receipt of the data. IGARD queried if the applicant had discussed the patient facing materials with the NU YOU support group as outlined in the HRA CAG support letter dated the 3rd June 2020; and NHS Digital confirmed that the applicant had engaged with the NU YOU in addition to the patient information leaflet and the responses were very favourable. IGARD noted the update from NHS Digital and commended the applicant on seeking the views of patients following the s251 approval. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the special conditions: a) To insert a special condition in section 6 replicating the specific condition outlined in the HRA CAG support, relating to KCL NHS FT staff training for the DSPT action plan. b) To remove the special condition in section 6 relating to the data processing agreements as this is not necessary.

	2. To update the data minimisation column in section 3(b) to include the indicative cohort size. 3. To amend section 5 throughout to ensure there is no assumption of positive outcomes, for example, the reference to the assumption that the outcomes **will** show the safety of the surgery. 4. In respect of the GP encounters: a) To clarify where the GP data is being obtained from. b) To confirm if the GP data is being linked to the data requested in this application. c) If **no** GP data is being obtained for linkage at the moment, to either remove the reference to GP data, or update the application to state this may be sought in the future. 5. In respect of the language in section 5: a) To revise the use of language throughout, including (but not limited to) the references to *"discarding"* data, *"commissionaires"* and *"caretakers"*. b) To update the description of how the data is stored and accessed on campus / the hospital. 6. To update section 5(a): a) To clarify that Ethicon are also involved with the manufacturing and sale of medical devices used in bariatric surgery. b) To make it explicitly clear that the PI is carrying out bariatric surgery in private practice. a) To update section 5(c) to clarify that this is a *"medium term study"* and not a long-term study. 7. To provide further clarity in section 11 of how any shortfall in funding vis-à-vis NHS Digital's charges is being met by the applicant. The following advice was given: 1. IGARD suggested that the applicant may wish to amend the application to reflect that a long-term study may be of use in the future. 2. IGARD advised that they would wish to review this application if it comes up for renewal, because as highlighted in the application, the study should be concluded within one year of receipt of the data.
3.5	<u>Intensive Care National Audit & Research Centre (ICNARC): FIRST-line support for Assistance in Breathing in Children (FIRST-ABC): A master protocol of two randomised trials to evaluate the non-inferiority of high flow nasal cannula (HFNC) versus continuous positive airway pressure (CPAP) for non-invasive respiratory support in paediatric critical care (Presenter: Charlotte Skinner) NIC-399287-T3X7W-v0.9</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES), Civil Registration (Deaths) data and Emergency Care Data Set (ECDS). In joint data controllership with Great Ormond Street Hospital (GOSH), the purpose is for two pragmatic randomised clinical trials (RCTs) aiming to evaluate the clinical and cost effectiveness of the use of High Flow Nasal Cannula (HFNC), as compared with Continuous Positive Airway Pressure (CPAP); when used as the first-line mode of non-invasive respiratory support in two distinct clinical scenarios: 1) in critically ill children requiring non-invasive respiratory support for an acute illness (step-up RCT); and 2) in critically ill children requiring non-invasive respiratory support within 72 hours of extubation following a period of invasive ventilation (step-down RCT).

	The aim is to include a total of 1,200 children, 600 in the step-down RCT and 600 in the step-up RCT, from around 25 NHS paediatric critical care units across England, Wales and Scotland. There is currently limited high-quality evidence to support whether HFNC or CPAP should be used as the first line mode of non-invasive respiratory support in critically ill children. In addition, previous research has also not studied the use of these interventions in the two distinct clinical scenarios outlined above. High quality evidence from RCTs is therefore urgently needed to help guide clinical decision making and to inform paediatric critical care clinicians and the wider NHS on the clinical and cost-effectiveness of HFNC versus CPAP. NHS Digital advised IGARD that section 3(b) (Additional Data Access Requested) contained duplicate information, in respect of the additional data requested, and would be amended accordingly. **Discussion:** IGARD welcomed the application and noted the importance of the study and commended both the applicant and NHS Digital on the quality of the application presented. In addition, IGARD praised the quality of the information provided on the applicant's public facing website which was very clear for the lay reader. IGARD noted and supported the update outlined by NHS Digital in respect of updating section 3(b) to remove any duplication of information. IGARD noted that the consent provided the appropriate legal gateway and was compatible with the processing outlined in the application. IGARD noted that the information relating to the specific Legitimate Interests Assessment for ICNARC, was located towards the end of section 5(a) (Objective for Processing), and asked that for consistency with other application relying on legitimate interests, this was moved to the beginning of section 5(a). IGARD suggested that if the patient information materials were revised in the future, the applicant may wish to give consideration to the term *"survival"*, which could suggest that this was the only type of data flowing, when in fact the breadth of data flowing was much wider. IGARD suggested that this could also be reflected on the public facing website. IGARD commended the circulation of the outputs to the families and scientific community, and suggested that further consideration should be given to a suitable national charity that supported families of children in intensive care that could disseminate any results of interest more widely. **Outcome:** recommendation to approve The following amendment were requested: 1. To ensure the reference to the specific Legitimate Interests Assessment for ICNARC is moved to the beginning of section 5(a). The following advice was given: 1. IGARD suggested that if the patient information materials are revised in the future, the applicant may wish to give consideration to the term *"survival"*, which could suggest that this is the only type of data flowing, when in fact the breadth of data flowing is much wider. IGARD suggested that this could also be reflected on the public facing website. 2. IGARD commended the circulation of the outputs to the families and scientific community, and suggested that further consideration should be given to a suitable

	national charity that supported families of children in intensive care that could disseminate any results of interest more widely.
3.6	Barts Health NHS Trust: The impact of COVID-19 on surgical care and outcomes in England (COVID-19 Surgical Observatory) - project 2 (Presenter: Charlotte Skinner) NIC-400985-V3D1C-v0.15 **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES), Civil Registration (Deaths) data and Emergency Care Data Set (ECDS); for the purpose of quantifying the risk of mortality associated with SARS-CoV-2 infection among tens of thousands of NHS patients that have already had surgery, and the effect of geographical location, ethnicity, and socioeconomic deprivation. The data will also quantify the excess population mortality attributable to COVID-19 among patients with surgical disease, including both direct surgical deaths and indirect deaths, such as those due to cancelled procedures or delayed presentation/diagnosis due to COVID-19. The requested data will be used to report the true risk of surgery with COVID-19 and prevent avoidable harm by providing data for policymakers and health leaders to plan the NHS strategy for a dynamic recovery of surgical services. It will also allow policymakers to balance the excess mortality associated with acquiring COVID-19 during surgical admissions, against the excess mortality due to delays in the provision of surgical treatment. **Discussion:** IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this data specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed, that in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that section 1 (Abstract) was updated confirming that the flow of date of death data, was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects. IGARD noted that the application received for review had minimal information within section 1, and asked that this was updated accordingly, for example, to ensure that **all** the data requested was accurately reflected. IGARD also queried the UK General Data Protection Regulation (UK GDPR) legal bases, as this was also missing from section 1, and were advised by NHS Digital, that the Article 9 (2) (j) and General Data Protection Article 6 (1) (e) were the legal bases being relied upon. NHS Digital advised IGARD, that following submission of the application, section 1 had been updated to reflect the missing information. IGARD thanked NHS Digital for the relevant updates and noted the update made to the application. IGARD noted the references in section 1 and section 5 (Purpose / Methods / Outputs) to *"surgical disease"*, and asked that this was amended to a more lay friendly term, such as *"disease able to be treated by surgery"*. IGARD also noted the language used within section 5(a) (Objective for Processing) to patients *"suffering"* from surgical disease, and suggested that these references were amended to refer to patients *"living"* with the condition. IGARD queried whether the researchers would have the full breadth of data they required to achieve the research aims; and advised that they would be supportive of the applicant receiving any additional flows of data, for example pseudonymised COVID-19 Second Generation Surveillance System (SGSS) and pseudonymised COVID-19 Hospitalisation in England Surveillance System' (CHESS) data, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5.

	Outcome: recommendation to approve The following amendments were requested: 1. To update section 1 confirming that the flow of date of death data, is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects. 2. To amend the references in section 1 and section 5 from *"surgical disease"* to a more lay friendly term, such as *"disease able to be treated by surgery"*. 3. To amend the references in section 5(a) and from *"suffering"* to *"living"* with the condition. The following advice was given: 1. IGARD queried whether the researchers would have the full breadth of data they required to achieve the research aims; and advised that they would be supportive of the applicant receiving any additional flows of data, for example pseudonymised SGSS and pseudonymised CHESS data, to ensure they were working with as full set of relevant data as possible; and that an appropriate justification for this additional data should be added in section 5.
4	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. 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.
5	<u>COVID-19 update</u> 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 23rd February 2021** can be found attached to these minutes as Appendix B.
6.1	<u>AOB:</u> <u>Information Governance</u> A member of NHS Digital's Privacy, Transparency and Ethics – COVID-19 Response Team, attended the meeting to provide a brief update / overview of ongoing work. 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 19/02/21

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-420710-X0H1P	ONS	17/12/2020	1. To provide a narrative exposition of why the combination of data in the TRE will be anonymous to the researchers in terms of specific GDPR considerations (which may be by way of providing a copy of the DPIA with this point addressed). 2. In respect of ethical approval, to either: a) Provide written evidence that support has been sought and given by NESDEC; **or** b) Provide a written justification as to why NESDEC support has not been sought (noting the significant scale of processing of personal data); c) To upload a copy of any relevant documentation to NHS Digital's CRM system. 3. To finalise the legal basis and the adoption of the NDO and make the necessary consequential amendments to the application and transparency materials.	IGARD members	Quorum of IGARD members	**IGARD Comments:** The conditions have been met but there are significant areas of risk with regard to the concept of "functionally anonymous" and whether the National Data-opt Out needs to be applied: 1. The assessments relating to anonymisation may come down on the wrong side of ICO guidance once produced. 2. Further clarity regarding what are considered "official statistics" and concern that the term may be used in too broader a sense to justify the application (with implications for exemption from the NDO).

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

Optum Health Solutions UK Limited Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 17th February 2021

Application & application version number: DARS-NIC-411161-G4K7X-v1.2 **Organisation name: University of Oxford** **Profession Advisory Group Agenda item: 4**
PAG supports this application. The patient has provided explicit consent. PAG did not see the application in the form that requested access to GDPPR data and following discussion would like to clarify that the researchers are unable to conduct their research purpose using the SCR data alone, including repeat access to the SCR. PAG requires that when results of the study are shared with any external organisations that a copy is also shared at the same time with the RCGP / BMA.

Attendees	Role	Organisation
Peter Short	Deputy Chair	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Pam Soorma	Secretariat	NHS Digital
James Gray	Senior Case Officer	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, 23rd February 2021

In attendance (IGARD Members):	Prof. Nicola Near (IGARD Specialist Research Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Catherine Day (DARS)
	James Gray (DARS)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)

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:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2.1	NIC-435152-C0H4N v0.3 Royal Devon and Exeter NHS Foundation Trust / NHS England (Quarry House) **Background:** This was a new application (v0.3) for an extract of Demographics data to understand the impact of biological and immunomodulatory therapy on SAR-CoV-2 (COVID-19) infection and immunity in patients with Inflammatory Bowel Disease (IBD). The Impact of Biologic Therapy on SARS-CoV-2 Infection and Immunity Study (CLARITY) is to investigate the impact of specific immunosuppressant drugs and shielding on COVID-19 infection and subsequent immunity following infection or vaccination and the results of the study will inform public health policy decisions for patients with IBD, alongside other patients treated on immunosuppressant drugs. NHS Digital noted this was classed as an urgent application relying on the Health Services Control of Patient Information (COPI) Regulation 2002 and would be progressed under NHS Digital's SIRO precedent.

	IGARD Observations: IGARD members were in agreement with NHS Digital's assessment that, as borne from the facts, that NHS England were not the Data Controller for this application and it should be updated to reflect the Royal Devon & Exeter NHS Foundation Trust as the sole Data Controller. IGARD members noted in section 8 (Funding Sources) the Royal Devon & Exeter NHS Foundation listed as the sponsor of the study, but in addition a number of pharmaceutical companies who were also providing additional "private" funding. IGARD members suggested that section 5(a) (Objective for Processing) be updated with a brief description of the involvement of the funders and any vested interest they may have in the research being undertaken, for example if they manufacture drugs used to treat IBD. In addition, an express statement should also be included to state that the funder(s) would not have influence on the design of the study or presentation of outcomes, nor suppress any of the findings of the research, as borne out of the facts presented (and if they did have such ability that this be clearly articulated) in section 5 (Purpose / Methods / Outputs) of the application, which forms NHS Digital's publicly available data release register. Furthermore, that section 5(e) should be updated to include a clear description of the nature and type of funding and any interests of the funders. IGARD noted that notwithstanding the application was proceeding under COPI, the applicant was still required to provide publicly available published GDPR compliant transparency materials which ideally should include, but not limited to, disclosure about the involvement of any pharmaceutical funders. IGARD members noted that section 5 of the application should be updated: • To include further detail around the non-consented cohort created, including an approximation of size; • to remove reference to "*inflammatory arthritis*" or to explain if this was part of a future project or this current project; • to reorder the paragraphs with regard to the ethics approval to be clear that Ethics cannot give approval for a COPI disseminations; and • to avoid describing the entire cohort with IBD as "*vulnerable*", since cohort members may be surprised to be thus labelled. IGARD members queried why NHS Digital were not undertaking the data linkage, in line with the NHS Digital DARS Standard for Data Minimisation in order to lessen the number of organisations handling the data. Should it not be possible, for practical reasons, a brief narrative should be included in section 1 (Abstract). IGARD noted that the outputs would be included in scientific journals and presented at future conferences, plus presented to representatives of the Crohn's and Colitis UK societies but suggested that all avenues with regard to immediate impact for clinicians be explored to ensure that outputs could be factored into any urgent guidance, as may be appropriate (for example liaising with the British Society of Gastroenterology). Notwithstanding the above points, IGARD members supported NHS Digital's assessment that the application would be approved under the NHS Digital DARS SIRO Precedent.

	Significant Risk Area: Transparency regarding the pharmaceutical funders of this study (in both the NHS Digital Release Register (the published section 5 of the application) and GDPR-compliant transparency materials).
2.2	NIC-378066-D9S8P-v0.6 University of Warwick (consented cohort) **Background:** This was a new application for the Recovery RS Trial: consented cohort for Civil Registration (Deaths) data extract. The applicant will process mortality data for inclusion in the RECOVERY-RS ~~Trial~~Trial, which is an adaptive trial, pragmatic, randomised controlled, open label, multi centred, effectiveness trial investigating the ventilation strategies in COVID-19, continuous positive airway pressure (CPAP), high flow nasal oxygen (HFNO) and standard care The objective for processing the NHS Digital data is to collect data on survival which forms part of the primary and secondary trial outcomes. The trial is funded by the National Institute for Health Research (NIHR) The application (v0.0) had been previously discussed at the COVID-19 response meeting on the 19th May 2020 and originally considered by the NHS Digital COVID-19 front door prioritisation meeting in May 2020, but NHS Digital noted that the application had not subsequently progressed at the time. NHS Digital noted that the applicant had subsequently re-submitted the application in 2021 for Civil Registration (Death) data for the full cohort alongside HES data to contribute to secondary outcomes and is still classed as a priority clinical trial. **IGARD Observations:** IGARD members reiterated that from a clinical perspective, this was an incredibly important trial with significant research outputs that could potentially influence current medical practice through the current pandemic, and any future work with regard to ventilation of patients, since none-invasive ventilation (via HFNO or CPAP) had a direct impact on reducing the demand on intensive care units and the use of ventilators which in turn reduces the impact on the whole system to deliver care and long term impact on patients. IGARD members suggested that section 1 (Abstract) should be updated to accurately reflect that the application had **not** been considered at an IGARD business as usual (BAU) meeting for a recommendation, but had only been considered at the COVID-19 response meeting, which could only provide comments or observations, as set out in its published standard operating procedure, and advised that they would wish to review this application again when it comes up for renewal, amendment or extension; and suggested that after this amendment had progressed via the SIRO route that this application would not be suitable for NHS Digital's precedent route (including SIRO) until it had had a full independent review and recommendation at an IGARD BAU meeting, via the usual DARS process. IGARD members noted that they were in agreement with NHS Digital's assessment that the consent materials were broadly compatible with the processing outlined in the application and noted that the applicant had taken on board previous IGARD comments and updated their subsequent consent material accordingly. IGARD members suggested that section 5(a) (Objective for Processing) of the application be updated to be clear that the application was for both mortality and Hospital Episode Statistics (HES) data, and that further narrative be included with regard to the flow of HES data.

	IGARD members noted reference to "*Data will be analysed using an anonymous trial identification number…*" and suggested that this was updated to more accurately reflect that the trial ID was "***pseudonymised***". IGARD members suggested that section 5 (Purpose / Methods / Outputs) be updated to include the indicative size of the cohort, and the overall size of the cohort. IGARD members noted in section 5(b) (Processing Activities) that "*there will be no attempt to re-contact patients*" but queried if the trial would in fact need to re-contact patients as part of any follow up, and suggested this sentence be removed, since inclusion of this statement would preclude any contact with participants following conclusion of the study. IGARD members noted in section 5(b) that "…*will not link the data further, as only the data linkages described are permitted under this agreement*…" and queried if the applicant would want to link to other data such as ICNARC data, as referenced in NIC-379982-F8G4M, since the inclusion of this definitive statement would preclude any linkage other than as described in the application.
	NIC-379982-F8G4M-v0.4 University of Warwick (S251 cohort) **Background:** This was a new application for the Recovery RS Trial: s251 cohort for Civil Registration (Deaths) data extract. The applicant will process mortality data for inclusion in the RECOVERY-RS Trial which is an adaptive trial, pragmatic, randomised controlled, open label, multi centred, effectiveness trial investigating the ventilation strategies in COVID-19, continuous positive airway pressure (CPAP), high flow nasal oxygen (HFNO) and standard care. The objective for processing the NHS Digital data is to collect data on survival which forms part of the primary and secondary trial outcomes. The trial is funded by the National Institute for Health Research (NIHR). The application (v0.0) had been previously discussed at the COVID-19 response meeting on the 19th May 2020 and originally considered by the NHS Digital COVID-19 front door prioritisation meeting in May 2020, but NHS Digital noted that the application had not subsequently progressed at the time. NHS Digital noted that the applicant had subsequently re-submitted the application in 2021 for Civil Registration (Death) data for the full cohort alongside HES data to contribute to secondary outcomes and is still classed as a priority clinical trial. IGARD Observations: IGARD members reiterated that from a clinical perspective, this was an incredibly important trial with significant research outputs that could potentially influence current medical practice through the current pandemic, and any future work with regard to ventilation of patients, since none-invasive ventilation (via HFNO or CPAP) had a direct impact on reducing the demand on intensive care units and the use of ventilators which in turn reduces the impact on the whole system to deliver care and long term impact on patients. IGARD members suggested that section 1 (Abstract) should be updated to accurately reflect that the application had **not** been considered at an IGARD business as usual (BAU) meeting for a recommendation, but had only been considered at the COVID-19 response meeting, which could only provide comments or observations, as set out in its published standard operating procedure, and advised that they would wish to review this application again when it comes up for renewal, amendment or extension; and suggested that after this amendment had

	progressed via the SIRO route that this application would not be suitable for NHS Digital's precedent route (including SIRO) until it had had a full independent review and recommendation at an IGARD BAU meeting, via the usual DARS process. IGARD members suggested that section 5(a) (Objective for Processing) of the application be updated to be clear that the application was for both mortality and Hospital Episodes Statistics (HES) data, and that further narrative be included with regard to the flow of HES data. IGARD members noted reference to "*Data will be analysed using an anonymous trial identification number…*" and suggested that this was updated to more accurately reflect that the trial ID was "***pseudonymised***". IGARD members suggested that section 5 (Purpose / Methods / Outputs) be updated to include the indicative size of the cohort, and the overall size of the cohort. IGARD members noted in section 5(b) (Processing Activities) that "*there will be no attempt to re-contact patients*" but queried if the trial would in fact need to re-contact patients as part of any follow up, and suggested this sentence be removed, since inclusion of this statement would preclude any contact with participants following conclusion of the study. IGARD members noted that the applicant had applied for and had gained conditional Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support for this application which would be applied on expiry of the Health Services Control of Patient Information (COPI) Regulation 2002. IGARD members noted in section 5(b) that "…*will not link the data further, as only the data linkages described are permitted under this agreement*…" and queried if the applicant would want to link to other data such as ICNARC or NWIS data as set out in the HRA CAG conditional s251 support letter, provided as a supporting document, since the inclusion of this definitive statement would preclude any linkage other than as described in the application. Noting that National Data Opt-Outs (NDO) were not upheld for data disseminated under COPI, but that the NDO would be upheld for data disseminated under the s251, that the applicant may wish to approach HRA CAG to amend their conditional support in order to get permission not uphold NDOs or be mindful of this fact should they wish to extend their current application. **Significant Risk Area:** the upholding of NDO's should the legal basis of the application move from COPI to S251 support.
3	<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.