Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 21st May 2020

In attendance (IGARD Members): Paul Affleck, Maria Clark, Kirsty Irvine (Chair), Dr Imran Khan, Dr Maurice Smith.

In attendance (NHS Digital): Dave Cronin, Louise Dunn, Karen Myers, Vicki Williams.

In attendance (NHS Digital) Observer: Joanna Warwick (2.1-2.4).

Not in attendance (IGARD Members): Prof Nicola Fear, Dr Geoffrey Schrecker.

1	**Declaration of interests:** Maria Clark noted professional links to the Society of Endocrinology (NIC-148364-RHMHS) but noted no specific connections with the or staff involved in the application and it was agreed that this was not a conflict of interest. Paul Affleck noted he was a member of Ministry of Defence Research Ethics Committee (MODREC) (relevant to NIC-377561-Z4B1L) but it was agreed that this was not a conflict of interest. Paul Affleck, Maria Clark, Kirsty Irvine, Dr Imran Khan and Dr Maurice Smith noted a professional link to the applicant at King's College London (NIC-377561-Z4B1L) but noted no specific connection with the application and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 7th May 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	Society of Endocrinology: MR1033 - CROSS-SECTIONAL MULTI-CENTRE STUDY OF UK ADULTS WITH CONGENITAL ADRENAL HYPERPLASIA (Presenter: Louise Dunn) NIC-148364-RHMHS **Application:** This was a renewal and extension application for identifiable Medical Research Information Service (MRIS) data, and an amendment to 1) add pseudonymised Civil Registration, Cancer Registration and Demographics data, and 2) to include the new Cohort Management and automated extract service products to replace future disseminations of the previously approved MRIS products. The Congenital adrenal Hyperplasia Adult Study Executive (CaHASE) was formed in 2003 to study the health status of Congenital Adrenal Hyperplasia (CAH) patients in adulthood. More patients with CAH survive into adulthood the study wishes to obtain information on the causes of morbidity and mortality, the purpose therefore is to obtain and share data that will inform on practice nationally and internationally. **Discussion:** IGARD noted the study's Patient and Public Involvement (PPI) and study had been ongoing for some time with the protocol for example dated 2003, and suggested that NHS Digital provide written confirmation that the applicant had in place a suitable communication plan for the next 12 months, which included (but not limited to) updating the

	study protocol, revising and refreshing the PPI, and ensuring participants were aware of their ongoing ability to withdraw from the study. IGARD noted that since the study Protocol did not appear to have been updated since 2003 the applicant may wish to review their various security practices including the secure transfer of data, and to consider whether the transfer of data was reflecting current best practice such as Secure File Transfer Protocol (SFTP). IGARD queried the Patient and Public Involvement (PPI) that had taken place so far and asked that section 5(b) (Processing Activities) was updated to reflect this, noting, for example the reference in section 5(c) (Specific Outputs Expected) to participants being key stakeholders. In addition, the application should set out any ongoing communication with the cohort and provide a further explanation of how the cohort would have the opportunity to withdraw consent from the study, since patient objections do not apply to consented studies. IGARD noted that those participants that had been recruited at a later stage, were issued with an updated version of the consent materials. IGARD queried if those members of the cohort that had been consented with the first iteration of the consent materials had also been sent the revised version, and asked for clarification of this. In addition, IGARD asked if participants had also received details of how to withdraw consent from the study. IGARD queried the reference in section 5(a) that stated *"Participants have consented to the use of their data to achieve the study aims.* ***They are therefore expecting*** *that their data be used in the ways described."* and suggested this was amended to state *"They will therefore not be surprised…."*. IGARD noted that section 5(a) (Objective for Processing) contained minimal historical information and asked that the beginning of this section was updated to ensure reference was made to the medical advances that had taken place over the last 60 years and to set the scene for current treatment. IGARD queried the inconsistencies within the application when referring to the identifiers held by NHS Digital and asked that this was revised to ensure that where appropriate the term *"gender"* was replaced with the term *"sex,* if *"sex"* was the data set held by NHS Digital. IGARD noted the references within the application to *"management of patients"* and asked that this was amended throughout to state *"management of conditions"*. IGARD noted that information that was usually provided in section 5(a) with regard to the Legitimate Interests had not been included, and asked that the beginning of section 5(a) was updated to ensure that the specific Legitimate Interest was linked to the processing and as expressed in the Legitimate Interest Assessment (LIA). IGARD queried the reference in section 5(b) to the study results being *"anonymised"* and asked that this was amended to correctly state *"anonymous"*. IGARD suggested the applicant may wish to apply for a List Clean of the data held on the participants to ensure they had the most up to date information, including addresses. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that there would be an expectation that the applicant had met their communication plan timeline; or that if this had not been met, that an explanation was provided of why planned goals had not been met. In addition, IGARD also advised that this application would not be suitable for NHS Digital's Precedent route. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices.

	Outcome Summary: recommendation to approve subject to the following condition: 1. NHS Digital to provide written confirmation that the applicant has provided a suitable communication plan for the next 12 months, which includes (but not limited to) updating the Protocol, revising and refreshing the PPI and ensuring participants are aware of their ongoing ability to withdraw from the study. The following amendments were requested: 1. To ensure that where appropriate the term *"gender"* is replaced with the term *"sex"* (if "sex" is the data set held by NHS Digital). 2. To update the beginning of section 5(a) to ensure reference is made to the advances that have taken place over the last 60 years and to set the scene for current treatment. 3. To amend the application throughout to change the reference from *"management of patients"* to *"management of conditions"*. 4. To update section 5 to reflect the PPI that has taken place, for example participants being stakeholders, to set out any ongoing communication with the cohort and to provide a further explanation of how the cohort will have the opportunity to withdraw consent. 5. To amend the reference in section 5(b) to the study results being *"anonymous"* not *"anonymised"*. 6. To clarify in section 1 that the cohort consented with the first iteration of the consent materials have also been sent the revised version, including details of how to withdraw consent. 7. To update section 5(a) to ensure reference to the specific Legitimate Interests as linked to the processing and as expressed in the LIA. 8. To amend the reference in section 5(a) that states *"They are therefore expecting that their data be used in the ways described"* with *"They will therefore not be surprised…."*. The following advice was given: 1. IGARD suggested the applicant may wish to apply for a List Clean of the data held on the participants. 2. IGARD suggested that noting the protocol doesn't appear to have been updated since 2003, the applicant may wish to review their various practices including the secure transfer of data, and to consider whether the transfer of data is reflecting current best practice. 3. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment; with an expectation that they will have met their communication plan timeline (or, if not, an explanation why plan goals have not been met). 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the condition would be approved Out of Committee (OOC) by the IGARD Chair
2.2	<u>The Royal College of Surgeons of England: National Vascular Registry - patient level HES and Civil Registration/Mortality data request (Presenter: Louise Dunn) NIC-59669-F6Y3W</u> **Application:** This was a new application for pseudonymised Civil Registration and Hospital Episode Statistics (HES) data, for the purpose of the National Vascular Registry (NVR), which is to improve the quality of care of patients having vascular surgery by providing high quality comparative information on clinical practice and outcomes and support quality improvement by NHS hospitals.

	The Registry was established in 2013 and collects data from NHS Trusts providing vascular surgery, in order to provide information on patient characteristics, pre-operative care, the range of surgery undertaken, and postoperative outcomes. Specific objectives of the NVR are, 1) To enable secondary care providers to improve the delivery of care to patients undergoing vascular surgery, 2) To provide comparative information on the process of care to NHS vascular units, 3) To provide comparative information on patient outcomes following surgery, and 4) To facilitate the development of effective change (quality improvement) initiatives and spread examples of best practice among NHS vascular services. **Discussion:** IGARD had a lengthy discussion on the participant consent materials and on balance IGARD agreed with NHS Digital's assessment that the materials were adequate, and that the data flow was compatible with the consent. IGARD queried what communication was being undertaken with the cohort, specifically how they were contacting those patients that had received emergency surgery and whose data was processed under s251 support. IGARD asked that a detailed communication plan was provided and in addition, that this included a plan for updating the consented cohort on how their data was being processed, for example via the website and Privacy Notice updates etc; and how participants were able to withdraw from the study. IGARD noted the COVID-19 questions outlined in supporting document SD1j, the NHS Health Research Confidentiality Advisory Group s251 amendment, and asked that the application was also updated to reflect these questions; and in addition, to clarify whether or not the consented cohort would also be studied in this way and to provide further detail in the communication plan about how that cohort would be updated on the wider study goals. IGARD also asked that the COVID-19 research outlined within supporting documents SD1J, and SD1K , the Healthcare Quality Improvement Partnership (HQIP) confirmation of support for S251 non-research application amendment, that the application was updated throughout to ensure this research and the processing that was being undertaken was reflected accurately. IGARD noted the information in section 3(c) (Patients Objections) that stated patient objections were applied, and asked that this was updated to reflect that the patient objections was 'mixed', as the National Data Opt-Out should not be applied to the consented part of the cohort. IGARD queried the information in section 5(b) (Processing Activities) that states the applicant was the principal Data Processor, and asked that this was updated to reflect the Data Processor status of the Clinical Effectiveness Unit (CEU). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. The applicant to provide a detailed communication plan to IGARD, which confirms: a) how they are contacting patients, particularly those who have received emergency surgery and whose data is being processed under s251 support. b) the plan for updating the consented cohort on how their data is being processed, for example, via website and Privacy Notice updates. c) how participants are able to withdraw from the study. 2. To update the application to reflect the COVID-19 research questions in the s251 amendment, and to clarify whether or not the consented cohort will also be studied in this way and to provide further detail in the communication plan about how that cohort will be updated on the wider study goals. The following amendments were requested:

	1. To update section 3(c) to reflect that patient objections is 'mixed' as the National Data Opt Out is not applied to the consented cohort. 2. To amend section 5(b) to reflect the Data Processor status of the CEU. 3. To update the application throughout to ensure this reflects the COVID-19 research and processing being undertaken. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.3	<u>Great Ormond Street Hospital for Children NHS Foundation Trust: Using National Congenital Heart Diseases Audit data to explore the impact of non-medical risk factors on late post-operative outcomes for children with complex congenital heart defects. (Presenter: Louise Dunn) NIC-219359-T5B0V</u> **Application:** This was a new application for pseudonymised Civil Registration data for the purpose of a study that uses National Congenital Heart Diseases Audit (NCHDA) data, to explore the impact of nonmedical risk factors on late, postoperative outcomes for children with complex congenital heart defects. The proposed research will use survival models to explore whether children from minority communities or deprived backgrounds experience worse outcomes than other children. This is important to understand since both children from a South Asian background and those living in addresses represented by the most deprived quintile are over represented amongst congenital heart patients. Further, the research intends to explore whether service provision in terms of antenatal diagnosis and case volume within children's specialist cardiac centres (hospitals) are linked to improvements in these specified outcomes for complex congenital heart conditions. **Discussion:** IGARD noted and commended the excellent Patient and Public Involvement (PPI) as outlined in the application. IGARD queried the processing location details in section 2(a) (Processing Location(s)), and noted that although the correct legal entity was referenced that this was updated to provide more detailed processing location details, rather than a generic address. IGARD noted the statement in section 5(b) (Processing Activities) *"Access to this record level data will be limited to only four members…"* and asked that this was amended to remove the reference to a specific number of researchers and to focus specifically on the roles. IGARD queried if funding was ongoing from the British Heart Foundation and asked that section 5 (Purpose / Methods / Outputs) of the application be updated to state that the funder will not have influence on the outcomes nor suppress any of the findings of the research / study. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To provide more processing location details in section 2(a). 2. To amend section 5(b) to remove reference to a specific number of researchers and to focus specifically on the roles. 3. To confirm within section 5 that the funder will not have influence on the outcomes nor suppress any of the findings of the research.
2.4	<u>Lightfoot Solutions UK Ltd: HES data through the Signals From Noise (sfn) tool (Presenter: Louise Dunn) NIC-359692-Q4X1C</u>

	Application: This was a renewal and extension application for pseudonymised Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS); and an amendment to 1) update the purpose of the agreement to reflect new work for NHS England and NHS Improvement to provide an Urgent Care Demand Growth Dashboard, and 2) to add in the new Emergency Care Data Set which is replacing HES A&E from 2019/20. The purpose is to support a tool used for 1) Providing access to summary and statistical analysis of patient data to customers with the objective of supporting a greater understanding of patient activity and flow to support activities in order to improve health provision; and 2) providing access to summary and statistical analysis of patient data to NHS commissioning organisations to support healthcare planning and service redesign. **Discussion:** IGARD queried the reference in section 5(e) (Is the Purpose of this Application in Anyway Commercial?) to the *"Lightfoot HES Group"* that was responsible for overseeing the governance for approving and on-boarding new clients.; IGARD referenced NHS Digital's Commercial Standard and asked that a satisfactory explanation was provided of the operation of the Lightfoot HES Group, including Terms of Reference or guiding principles, composition of the group and other internal arrangements, for example minutes etc. IGARD queried why the data was being accumulated and not deleted on a rolling basis and asked that a justification of the accumulation of data was provided and, in addition, that an explicit rationale was provided of why historical data was being retained. IGARD noted the references throughout the application to the COVID-19 work being undertaken, and asked that the application was amended to ensure that any references to COVID-19 were expanded to include further details of how this would be researched and what difference this would make to the software and outputs. IGARD noted the role of C4L and queried if they had been considered as a joint Data Processor, and were advised by NHS Digital that they had assessed the role of C4L and were satisfied that they were not considered a joint Data Processor as C4L were only hosting the server and did not own it. IGARD noted the assessment and asked that this information was noted in section 1 (Abstract). IGARD noted the information provided in section 5(e) in terms of the commercial aspect and asked that this was updated to clarify that the income was generated from the software licence and that the data itself was not being sub-licensed. IGARD suggested that the end of section 5(d) (Benefits) (iii) (Yielded Benefits) was incomplete and asked that this was updated to insert the relevant missing information. In addition and noting the applicant had had data since 2017, IGARD asked that further examples of and dates of yielded benefits to support the review of future iterations of the application were provided. IGARD queried if NHS Digital had received the applicant's Data Protection Impact Assessment (DPIA) since it was not part of the supporting documents provided for review, and were advised by NHS Digital that they had received the document from the applicant. IGARD noted the document had been received and asked that section 1 was updated confirming that NHS Digital had reviewed the applicant's DPIA and were satisfied with its content. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, in addition, IGARD noted that The International Organization for Standardization (ISO) certificate linked to from within within the Privacy Notice was out of date and asked that it was replaced with the latest one. IGARD noted reference to a number of technical phrases and words within the application and suggested that it be updated to ensure that technical language was used only where

	necessary; and where necessary that it also had an explanation in language suitable for a lay reader. A number of acronyms were noted in section 5 (Purpose / Methods / Outputs), and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use, be clearly defined and that it also had a further supportive explanation in language suitable for a lay reader. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide a satisfactory explanation of the operation of the Lightfoot HES Group, including Terms of Reference or guiding principles, composition of the group and other internal arrangements, for example minutes etc. 2. To provide justification of why data is being accumulated and not deleted on a rolling basis; and an explicit rationale of why historical aged data is being retained. The following amendments were requested: 1. To amend the application throughout to ensure that the reference(s) to the COVID-19 work being undertaken is expanded to include further details of how this will be researched and what difference this will make to the software and outputs. 2. To clarify in section 1 that NHS Digital have assessed the role of C4L and are satisfied that they are not considered a joint Data Processor. 3. To clarify in section 5(e) that the income is generated from the software licence and that the data itself is not being sub-licensed. 4. To update section 5(d) (iii) to complete the information provided and provide further examples and dates to support the review of future iterations of the application. 5. To update section 1 to confirm that NHS Digital has reviewed the applicant's DPIA and are satisfied with its content. 6. To update the ISO reference with the correct link within the Privacy Notice. 7. To update the application to ensure the use of technical jargon is used only where necessary; and where it is necessary, to be also written in language suitable for a lay reader 8. To amend section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.5	<u>The University of Manchester: Evaluating the NHS Diabetes Prevention Programme (NHS DPP): the DIPLOMA research programme (Diabetes Prevention – Long term Multimethod Assessment) (Presenter: Dave Cronin) NIC-196221-K4K3Y</u> **Application:** This was a new application for pseudonymised National Diabetes Audit (NDA) data for the purpose of a research programme the aim of which is to provide a comprehensive

	assessment of the implementation, delivery and outcomes of the NHS DPP to inform commissioning. The data will be used in three of eight work packages in the overall DIPLOMA research project. These are: Work package 1: Access and Equity – the aim is to assess the accessibility of the NHS DPP and identify inequalities in access; Work package 5: Comparative Effectiveness – the aim is to examine whether the NHS DPP leads to a reduction in the prevalence of Type 2 Diabetes and other outcomes related to Type 2 Diabetes compared to those without access to the NHS DPP; and Work package 7: Economic Evaluation – the aim is to explore the cost-effectiveness of the NHS DPP, from the perspective of the NHS and Personal Social Services. The application was been previously considered on the 27th June 2019 when IGARD had deferred pending: confirmation in writing that the work being undertaken has been reviewed and approved by NIHR, the funder; in order to answer questions 2 and 3 of work package 1, work needs to take place under work packages 3 and 4 since some of research questions of work package 1 can be answered by additional work under work packages 3 and 4 and to confirm why the data is not being used for other work packages and only used for work package 1; to update section 5 to ensure it reflects the new current project and to be also written in language suitable for a lay reader; confirmation that the survey data is not supplied by NHS Digital, but by an alternate data supplier; to update the abstract and section 4 that the fair processing notices for both Data Controllers have been reviewed against NHS Digital's criteria for privacy notices; to update section 3 to include an explanation of data minimisation efforts undertaken for the NDA dataset; clarification why the applicant needs to receive GP data from the NDA, given they will be receiving this data from the CPRD dataset; to update section 5 to clarify why in particular 'learning disability' has been flagged, as opposed to other disability characteristics; clarification why the NDA disclosure controls apply. **Discussion:** IGARD welcomed the application and noted the importance of the research. IGARD noted that the application had changed significantly and therefore not all the previous comments made were now applicable, however the application had been updated to reflect any relevant comments previously made. IGARD noted similarities between some of the work packages listed in the wider project that did not come under this application, and asked that the applicant provide confirmation that that they did not wish to include any other work packages as being work packages that benefit from the flow of data under this application. In addition, and so as not to constrain themselves in the future use of this data, suggested that they definitively describe which datasets were being used for the projects outlined in this application in section 3(b). IGARD also asked that written confirmation was provided that the applicant had reviewed the data requested and that all the relevant work packages that would potentially need this data had been included within this application. IGARD queried why supporting document 3.0, the 'Ethics Approval from the NHS Health Research Authority North West – Greater Manchester East Research Ethics Committee' had been provided, in light of the information in section 7 that stated ethics approval was not required and asked that section 1 was updated clarifying that Ethics Approval was for the wider project only and not in respect of the processing under this application. If however Ethics Approval did support this application, to update the application accordingly. There was a lengthy discussion with regard to the references in section 5 (Purpose / Methods / Outputs) *"learning disabilities"* and asked that this was updated to be clear that where this was referenced, it was addressing an NHS England policy focus on reducing inequalities and unwarranted variation in health outcomes and was not, as currently written, a specific protected characteristic as outlined in the Equalities Act.

	IGARD noted the answers to the previous deferral points in section 1, and asked that the response provided to question 2 in reference to the different work packages was also replicated in section 5(a) (Objective for Processing). IGARD queried the information provided in section 5(c) (Specific Outputs Expected) when describing the outputs and timeframes, and asked that the language was revised to ensure these were realistic and achievable. IGARD noted the information provided in section 5(d) (Benefits) in relation to the benefits and asked that this was updated to clarify that the key benefit flowing from this study was to test the efficacy of the DIPLOMA Programme. A number of acronyms were noted in section 5(a), and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use, be clearly defined and that it also had a further supportive explanation in language suitable for a lay reader. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve subject to the following condition: 1. The applicant to confirm that they do not wish to include any other work packages as being work packages that benefit from the flow of data under this application, so as not to constrain themselves in the future use of this data by: a) Definitively describing which datasets are being used within this application; b) Provide confirmation that the applicant has reviewed the data requested and all the relevant work packages that will potentially need this data have been included within this application. The following amendments were requested: 1. To update section 1 to clarify that Ethics Approval, although provided as a supporting document is for the wider project only and not in respect of the processing under this application (or if the Ethics does support this application, to update the application accordingly). 2. To amend section 5(a) to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader. 3. To update section 5(a) with the response from question 2 noted in Section 1in reference to the different work packages. 4. To revise the language in section 5(c) when describing the potential outputs and timeframes to ensure that these are realistic and achievable. 5. To clarify in section 5(d) that key benefit flowing from this study is to test the efficacy of the DIPLOMA Programme. 6. To update section 5 where referencing learning disabilities to be clear this is addressing an NHS England policy focus on reducing inequalities and unwarranted variation in health outcomes. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment.

	2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.6	<u>King's College London: ArmeD SerVices TrAuma RehabilitatioN OutComE Study (ADVANCE) (Presenter: Dave Cronin) NIC-377561-Z4B1L</u> **Application:** This was a new application that came to IGARD for advice on the consent materials. The study aims to investigate the long-term outcomes of battlefield trauma casualties and to compare these outcomes to those of a similar group of non-battlefield trauma individuals. All participants will be service men and women who either sustained significant battlefield trauma while on deployment with the British Armed Forces or who were deployed but not injured. **Discussion:** IGARD noted that a member of the study team was a member of IGARD. IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed. In respect of the participant consent materials, IGARD noted that the purpose of the study was to look at battlefield trauma, however it was not clear within the documentation provided if the trauma was physical, severe physical or mental, and asked that this made clear within the materials. IGARD queried the reference within the consent materials to the data that was being obtained relating to *"hospitalisation"* and suggested that in order to future proof the materials, this was removed and replaced with a more generic phrase in order to also capture outpatient appointments, treatment and hospital day visits, since 'hospitalisation' meant an overnight stay in a hospital setting. IGARD noted that the study follow-up period was 20 years and although that was a substantial length of time suggested that whilst it was important to provide participants with an indication of this, the applicant may wish to consider an open-ended statement, should the study be extended in the future, or indeed beyond the life of the participant. IGARD queried how the study would stay in touch with the cohort and suggested that, in order to develop the study further, the applicant may wish to further consider the regularity of contact. IGARD discussed the payment for taking part in the study, and suggested that the applicant may wish to refer to the 2014 'HRA Ethics guidance – Payments and Incentives in Research' for further guidance. IGARD also discussed the cash prize draw that participants would be entered into, and advised that whilst they would not be taking a view or offering advice as to whether it complied with the relevant gaming legislation, suggested that the applicant should satisfy themselves that that they were not inadvertently running a lottery; and that it may be useful to provide participants with an idea of the likely number of entrants into the draw. In respect of the application, IGARD noted that this was still work in progress, however asked that this should provide clear details of the study group, the comparison study group and what kind of trauma was being studied. **Outcome:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed.

	1. In reference to the consent materials: a) To be clear within the consent materials if the study is looking at physical, severe physical or mental trauma. b) In order to future proof the consent materials, to remove reference to "hospitalisation" and to use a more generic phrase in order to capture outpatient appointments, treatment and hospital day visits. c) Whilst useful to give an indication of a follow-up of 20 years, the applicant may wish to consider an open-ended statement, should the study be extended in the future. d) In order to develop the study further, the applicant may wish to consider how they keep in touch with the cohort and the regularity of contact. 2. IGARD suggested that in respect of the payment for taking part in the study, the applicant should refer to the 2014 'HRA Ethics guidance – Payments and Incentives in Research'. 3. IGARD are not taking a view or offering advice as to whether it complies with the relevant gaming legislation, in respect of the cash prize draw, the applicant should satisfy themselves that that they are not inadvertently running a lottery; and that it may be useful to provide participants with an idea of the likely number of entrants. In relation to the application, the following observations were made: 1. The applicant should provide clear details of the study group, the comparison study group and what kind of trauma is being studied.
3	<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. • NIC-72180 University of Glasgow • NIC-11544 Birmingham Women's & Children's NHS FT • NIC-195235 University of East Anglia IGARD welcomed the three applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and Control of Patient Information (COPI) regulation applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	<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 Control of Patient Information (COPI) regulation urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 12th and 19th May 2020 can be found attached to these minutes as Appendix B. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.

5	AOB:
5.1	**IGARD Deputy Chair and Alternate Deputy Chair** It was discussed and agreed by IGARD members that Geoff Schrecker would continue to be the IGARD Deputy Chair and Maria Clark would continue to be the Alternate Deputy Chair from 13th June 2020 for one year, as per agreed procedures. 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.

Annex A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 15/05/20

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-359603-D2Q6M	Care Quality Commission (CQC)	07/05/2020	1. To take advice from NHS Digital Security and subsequently either clarify why Cap Gemini are not considered a Data Processor or in the event that they are considered a Data Processor to add them to the DSA and amend the application accordingly.	Alternate Deputy Chair	Alternate Deputy Chair	The following additional amendments were requested: To include a further explanation of the advice from NHS Digital Security in section 5(a). To use the name CapGemini consistently throughout the application
NIC-343158-Z2L4D	NHS Gloucestershire CCG	23.05/2020	1. To update the application to reflect how this Commissioning application has a Risk Stratification element.	IGARD Members	Quorum of IGARD Members	N/A
NIC-91972-S9W9T	3M United Kingdom PLC	09/04/2020	1. 3M United Kingdom PLC to provide confirmation that they have not launched the commercial Tool.	IGARD Chair	IGARD Chair	N/A
NIC-77142-Q4D1D	University Hospitals Birmingham NHS FT	09/04/2020	1. To confirm that the cohort supplied by NCRAS is matched to the cohort supplied by UK Transplant registry by NHS Digital and that only those patients from the NCRAS cohort who are also in the UK Transplant Registry cohort have their data transferred to University Hospital Birmingham NHS FT.	IGARD Members	IGARD Members	N/A

			2. To update section 3(c) to reflect the obligations of NHS Digital in respect of patient objections as set out in SD1.1.			
NIC-209200-S9H5R	Royal College of Psychiatrists	19/03/2020	1. NHS Digital to satisfy itself and provide written confirmation to IGARD that both Data Controllers have published revised Privacy Notices, ensuring that they are compliant with the notice requirements under the GDPR and which meets NHS Digital's published 10a Transparency Standard. 2. To provide written confirmation that NHS Digital is not flowing any maternity-related data.	IGARD Members	IGARD Members	To update the URL to the HQIP privacy notice in the amended application The condition hasn't been met but IGARD is content that any risk is reasonably mitigated by adding the Special Condition *(HQIP must review their Privacy notice and ensure that this is in line with the ICO's checklist specifically to address the points which NHS Digital have raised regarding the following points 4,8,14, and 16. within 3 month of the signing of the agreement.)* and on that basis IGARD is content that data can flow under the amended agreement.

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

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

- None notified to IGARD

Appendix B

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response meeting held via videoconference, Tuesday, 12 May 2020

In attendance (IGARD Members): Paul Affleck, Kirsty Irvine (Chair), Geoffrey Schrecker.

In attendance (NHS Digital): Vicky Byrnes-Watts, Garry Coleman, Catherine Day, Liz Gaffney, Karen Myers (Observing), Vicki Williams.

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 DARS process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	NIC-374190-D0N1M Genomics England **Background:** This was an update to the application presented to the COVID-19 Response meeting on the 28th April and 5th May 2020. The GenOMICC (Genetics of Mortality in Critical Care) study aims to identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury. The applicant had provided additional documentation including an updated protocol, consent materials, patient information leaflets and data flow diagram for consideration alongside an updated application which outlined the data sets required with additional information provided in section 5. **IGARD Observations:** NHS Digital gave an analysis of their queries and questions raised after reviewing the new documentation provided by, and discussions with, the applicant. IGARD members agreed with the analysis provided by NHS Digital. IGARD members noted that the key issues with regard to the materials provided were to ensure that NHS Digital were clearly referenced, that reference was made to identifying data flowing to and from NHS Digital, and to ensure that no inadvertent barrier was put in place in current documentation that would stop any onward sub licencing or onward sharing. IGARD members noted that the applicant should ensure their suite of documents contained consistent wording throughout, for example reference to the legal basis or how a cohort member can opt out.

	IGARD members reviewed the consent materials provided and noted that it should be clear that the applicant was obtaining **consent** from anyone aged 16 years and over. For those aged under 16 years of age (15 years and 364 days and under), **assent** should be obtained where appropriate plus parental / guardian consent. Currently, the consent forms were headed in such a way that a 16 year old could sign an assent form, which was inappropriate since in this context they were considered an adult for consent purposes. IGARD members also noted that it was good practice to ensure that a process was in place for the obtaining of consent for those in the study who subsequently turned 16 years of age and could sign their own consent forms. This was particularly important since assent and consent from a parent / guardian may have been obtained when the young person was very ill in hospital. IGARD noted reference to a personal consultee consent form and telephone script for obtaining consent; since they presented their own challenges, IGARD members were working on the assumption that the Ethics committee had considered them in detail. IGARD members noted that the Patient Information Sheet v2.1 noted under the header 'what data is looked at' reference to '*electronic copies of all your records from the NHS, your GP and other organisations*' and suggested that this should be amended to reflect accurately that this would be a patients' '*health information from your records…*'. IGARD members suggested for sub licencing and further onward sharing that it be clear who the Data Controller would be for any data held at a local data store, and that appropriate rigour be put in place for the control of data going to local data stores. In addition, and also to ensure consistency with applications of a similar nature with sublicensing or onward sharing, that where data is onwardly-shared that a careful analysis of the data was undertaken to ensure appropriate IG safeguards in place to ensure that the data cannot be re-identified.
2.2	<u>NIC-190086-F5Z7B St Georges, University of London</u> **Background:** This was an update to the application presented to the COVID-19 Response meeting on the 5th May 2020 for advice. The applicant wishes to expand the scope of their current Data Sharing Agreement (DSA) to get approval for additional COVID-19 related work which would involve changes to data specifications. Using Hospital Episode Statistic-Office for National Statistic (HES-ONS) linked data the applicant wishes to evaluate which persons from existing cohorts were diagnosed with COVID-19 and if any of these persons went on to die from cardiac or COVID-19 related disease. In addition to requesting COVID-19 related ICD and OPCS codes to existing filters, the applicant wishes to receive 2019/20 Admitted Patient Care (APC) and Critical Care (CC) (not Outpatient (OP) or Accident & Emergency (A&E)). The information may give the applicant the opportunity to evaluate for COVID-19 risk factors which may be relevant to Public Health England (PHE) and the medical community worldwide. The applicant had provided additional background to Cardiac Risk in the Young (CRY) which aims to analyse COVID-19-related outcomes in a large series of young individuals who underwent cardiac screening with CRY between 2008 and 2018 and additional s251 documentation had been provided for consideration. **IGARD Observations:**

	NHS Digital gave an analysis of their queries and questions raised after reviewing the new documentation provided by the applicant. IGARD members agreed with the analysis provided by NHS Digital. IGARD members noted the effort undertaken by the applicant to build a case that their current s251 support covered the addition of the new datasets. However, IGARD members noted that purpose outlined in the DARS application did not seem to fit the purpose articulated in the s251 support currently in place, but that it wasn't for IGARD members to provide a Health Research Authority Confidentiality Advisory Group (HRA CAG) opinion on whether the s251 support could be extended in such a way. IGARD members noted this was a worthwhile and interesting study but suggested that the applicant, when building their amendment submission for HRA CAG, should look at how the intervention or change would influence clinical practice, which may be over the longer term. Also, to consider the question they are seeking to answer and how they achieve that with the data that NHS Digital can supply. IGARD Members noted that they would facilitate this request via HRA CAG and support the applicant with the process, and that by using the s251 route should future-proof their permissions and enable the applicant to use the data for wider purposes (but still in line with the purposes outlined in the application and benefiting health and social care in England and Wales). In addition, IGARD members noted that the applicant may also wish to update their privacy notice to align with the amendments requested.
2.3	<u>NIC-15625-T8K6L Clinical Practice Research Datalink (CPRD)</u> **Background:** the applicant wishes to extend the current Data Sharing Agreement (DSA) to include linkage with PHE's Second Generation Surveillance System (SGSS) data specifically for COVID-19 test result and linkage with PHE's COVID-19 Hospitalisation in England Surveillance System (CHESS), both datasets held by NHS Digital. The linkage would be permitted by PHE and could be conducted under the recent COVID-19 notices under Reg 3 of the Health Service Control of Patient Information (COPI) Regulations 2002. NHS Digital had brought this application to the meeting for advice. **IGARD Observations:** IGARD members noted that, on the face of the information presented, the two datasets of CHESS and SGSS seemed to fit neatly with the CPRD's general aims and outputs and was in line with the other datasets that CPRD held. It would appear that COPI would appear to be an option available, provided that the purpose for processing those CHESS and SGSS datasets fitted with the COPI Regulation 3(1). In addition, CPRD would need to clearly articulate the purpose in section 5 of the application. However, using the COPI notices would have limitations and drawbacks in that it is time limited and the application would therefore need a sunset clause or other exit mechanism. IGARD members noted that the applicant would then need a clear exit arrangement in place for any data onwardly shared. IGARD members noted the advantages of using the s251 support that the applicant already had in place for data held under this application and suggested that the applicant may wish to

	extend their s251 support to include these two additional datasets by submitting an amended application to Health Research Authority Confidentiality Advisory Group (HRA CAG). IGARD Members noted that they would facilitate this request via HRA CAG and support the applicant with the process. IGARD members noted that by using the s251 route would future-proof their permissions and enable the applicant to use the data for wider purposes beyond direct COVID-19 response as constrained by the wording of the COPI regulations (any use would always still have to be in line with the purposes outlined in the application and benefit health and social care in England and Wales). IGARD members noted that special conditions set out within CPRD's current live application would need to be carried over and would apply to the additional datasets and emphasised that these would need to be carefully complied with, in particular conditions relating to onward worldwide sharing and the need for analysis and recording of a clear benefit to health and social care in England and Wales. IGARD members discussed why it was imperative that the special conditions agreed with NHS Digital are included and compliance with those special conditions was carefully documented. The reasons for this include, but are not limited to, helping rebut any suggestion that onward sharing or sublicensing was profiteering from the nation's misfortune in the current pandemic environment.
2.4	<u>NIC-365354 -R3M0Q University of Oxford</u> **Background:** This was a verbal update to the application presented to the COVID-19 Response meeting on the 28th April and 5th May 2020. This was an amendment application that had previously been approved by NHS Digital's SIRO on 31 March 2020 for access to data for the Randomised Evaluation of COVID-19 thERapY (RECOVERY). The study aims to compare several different treatments that may be useful for patients with COVID-19 and the new trial was classed as an 'Urgent Public Health Research Study'. The update included the approval of the Public Health England (PHE) COVID-19 Hospitalisation in England Surveillance System (CHESS), PHE's Second Generation Surveillance System (SGSS) and NHS Business Service Authority (BSA) prescribing data from information governance (IG) and how this will be incorporated into the Data Sharing Agreement (DSA). **IGARD Observations:** NHS Digital noted the applicant's thanks in relation to IGARD's advice on the consent materials for children. In addition, NHS Digital noted that the Information Governance (IG) Directorate had approved the CHESS, SGSS and NHS BSA prescribing data as covered by the consent materials provided and that the data had been disseminated under an amended application. IGARD members noted that best practice was for those members of the cohort reaching the age of 16, and therefore expressly classed as an adult for this type of trial, should be re-consented on appropriate consent forms and that this could be done by way of a letter to the relevant cohort members, which could be support via a list clean undertaken by NHS Digital.
2.5	<u>NIC-372789-B6Q2B Public Health England (PHE)</u>

	Background: This was a verbal update to the application presented to the COVID-19 Response meeting on the 5th May 2020 The application is to assess the overall transmissions of COVID-19 against the transmission for people currently at a stated address. Presently there is no consistent data indicating household contact status within COVID-19 surveillance and monitoring datasets held by PHE in order to model scenarios. Existing NHS Digital datasets can be used to identify individuals with the same address and this linkable asset would enable PHE to undertake a range of analysis to support the pandemic response. NHS Digital had met with the team to feedback IGARD's observations and in return the applicant had fed back updates on the observations made, including: • Interventions - PHE confirmed that where any significant findings are made that would warrant advice on policy, these will be fed to the PHE Incident Director as part of the incident response who would incorporate this into the advice to government as appropriate. • Type of data – PHE confirmed that they did not require personal identifiers included in the dataset and would work with NHS Digital to agree on the precise terminology. • Onward sharing/potential mis-interpretations data - PHE confirmed that they did not plan to share the data with any third parties. For any future research requests for totally separate uses of the data (e.g. a university researcher making an approach for their specific use) then PHE agreed that going through the established NHS Digital processes including research ethics/governance would be appropriate. PHE agreed with the risk identified regarding mis-interpretation of the data and that it needed very careful analysis and would not want to onwardly share the data. **IGARD Observations:** IGARD members noted these points and thanked PHE for providing an update to the meeting.
2.6	<u>Update on GP Data for Planning and Research</u> **Background:** This was a verbal update to the item presented to the meeting on the 21st April 2020. There is high demand for GP data in support of urgent care planning, audit and research directly related to COVID-19 and there is a burden on General Practice to ensure legitimate, controlled and proportionate data release. The British Medical Association (BMA) and Royal College of General Practitioners (RCGP) have requested a tactical solution to meet the demand and relieve the burden / responsibility. **IGARD Observations:** IGARD members noted and thanked the Associate Director Data Access for providing an update to the meeting following his meetings with colleagues in NHS Digital and across the BMA and RCGP. Both NHS Digital and IGARD members agreed that further work was required to support the applications which would come via the Data Access Request Service (DARS) process to IGARD to a Thursday business as usual meeting, and that this be discussed at future IGARD

	meeting, including templated applications and precedent routes once a number of templated applications had been approved via IGARD. IGARD noted that all applications that went via any agreed precedent route would be available to review under their current Terms of References as part of the oversight and assurance sessions each Thursday.
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.

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting held via videoconference, Tuesday, 19 May 2020

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

In attendance (NHS Digital): Vicky Byrnes-Watts, Catherine Day, Louise Dunn, Karen Myers (Observing), Kimberley Watson, Vicki Williams.

3	**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 DARS process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	<u>NIC-15625-T8K6L Clinical Practice Research Datalink (CPRD)</u> **Background:** This was a verbal update to the application presented to the COVID-19 Response meeting on the 12th May 2020 for advice. The application was an amendment to extend the current Data Sharing Agreement (DSA) to include linkage with PHE's Second Generation Surveillance System (SGSS) data specifically for the COVID-19 test result data and linkage with PHE's COVID-19 Hospitalisation in England Surveillance System (CHESS), both datasets held by NHS Digital. The linkage is permitted by PHE and should be conducted under the recent COVID-19 notices under Reg 3(4) of the Health Service Control of Patient Information (COPI) Regulations 2002. NHS Digital noted that the application had been updated in line with the advice given last week however IGARD had not been provided a copy of the revised application for review. **IGARD Observations:** IGARD members noted that the application had been updated in line with previous observations at the meeting on the 12th May 2020 and suggested that a copy of the updated application be provided by NHS Digital for review by IGARD members out of committee and any comments made would be captured in next Tuesday's COVID-19 Response meeting on the 26th May for transparency of process. IGARD members reiterated their comments that relying on COPI notices would have limitations in that it is time limited. NHS Digital noted that a sunset clause had been inserted as a special condition in section 6 of the application. IGARD members queried the process for any data obtained relying on COPI that would be subsequently shared under a sub license: NHS Digital confirmed that an additional special condition had been included in section 6 of the application that any sub-licensees would have

	to destroy any data that had flowed to them under COPI within 30 days of the sunset clause being enacted. IGARD members noted again the advantages of using the s251 support that the applicant already had in place for data held under this application, and NHS Digital confirmed that the applicant was in discussions with HRA CAG to progress. In summary, and noting that IGARD members have not reviewed the updated application and may have additional comments following a review, IGARD were supportive of the verbal update given by NHS Digital; they were supportive of the applicant relying on COPI Reg 3 and supportive of the applicant's ongoing work to progress s251 via HRA CAG. **Subsequent to the meeting:** NHS Digital confirmed that following an internal prioritisation call on the 19th May that until the HDRUK prioritisation had been confirmed NHS Digital would not be forwarding the updated application to IGARD for review.
2.2	<u>NIC-379982-F8G4M University of Warwick (S251 cohort)</u> **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) **IGARD Observations:** From a clinical perspective, the IGARD clinicians noted that 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 non-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. The IGARD clinicians suggested that NHS Digital should prioritise this application and processing required to expediate the release of data. IGARD members noted that Health Service Control of Patient Information (COPI) Regulations 2002 Regulation 3 appeared to be an option available for the legal basis for the dissemination of data whilst the applicant simultaneously advanced their s251 support amendment. IGARD members queried the progress of s251 support and NHS Digital noted that work was ongoing and had a number of queries. IGARD members that it was not for them to provide a Health Research Authority Confidentiality Advisory Group (HRA CAG) opinion on whether the s251 support could be extended or amended for this application. IGARD members noted reference to a co-chief investigator based at the Queen's University Belfast and that the Belfast University's logo's had been used on a number of supporting documents provided and suggested that NHS Digital investigate whether the Queen's University should be considered a Data Controller or if relevant honorary contracts were in place with the applicant. IGARD members noted that Data Controllership was an assessment

	of fact and suggested that if the Queen's University did not have a Data Sharing Framework Contract with NHS Digital that a relevant special condition be inserted into section 6 of applicant's application. In addition, IGARD members noted that the study website was informative. In summary IGARD members were supportive of the applicant relying on COPI Reg 3 and supportive of the applicant's ongoing work to progress s251 via HRA CAG.
2.3	<u>NIC-378066-D9S8P University of Warwick (consented cohort)</u> **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 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) **IGARD Observations:** From a clinical perspective, the IGARD clinicians noted that 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. The IGARD clinicians suggested that NHS Digital should prioritise this application and processing required to expediate the release of data. IGARD observed that the existing consent materials were broadly compatible with the proposed processing, but in order to give long term support to this important study, suggested amendments (without prejudice to any further comments from NHS Digital or IGARD upon a future detailed review): • there was a variation of wording across the three types of consent forms provided for review: 'consent form on commencement', 'consent form consultee' and 'consent form deferred consent' and suggested that the 'consent form consultee' section 7 wording be updated to align with section 5 of the other two consent forms provided. • To update the patient information sheet to explicitly state the data flows and organisations involved, including NHS Digital. In addition, IGARD members noted that the study website was helpful and informative. IGARD members noted reference to a co-chief investigator based at the Queen's University Belfast and that the Belfast University's logo's had been used on a number of supporting documents provided and suggested that NHS Digital investigate whether the Queen's University should be considered a Data Controller or if relevant honorary contracts were in place with the applicant. IGARD members noted that Data Controllership was an assessment of fact and suggested that if the Queen's University did not have a Data Sharing Framework

	Contract with NHS Digital that a relevant special condition be inserted into section 6 of applicant's application. In summary IGARD members were supportive of the applicant relying on COPI Reg 3 and supportive of the applicant's ongoing work to update their patient information sheets and consent materials.
2.4	<u>NIC-374223-P4P4L National Institute for Health Research (NIHR)</u> **Background:** This was a discussion item with regard to a Health Data Research (HDR) UK consented research cohorts to identify susceptibility and resilience factors in cohorts for specific COVID-19 research in order to better understand and protect vulnerable populations. NHS Digital were seeking guidance on whether this application would be suitable for the Health Service Control of Patient Information (COPI) Regulations 2002 route alongside seeking s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG) since the applicant had stated they did not wish to re-consent their current cohorts - or whether it was possible to uplift the applicant's current consent materials. **IGARD Observations:** IGARD members were unclear if the Trusted Research Environment (TRE) outlined in the data flow diagram provided, was the same NHS Digital TRE presented to IGARD previously and asked that the interrelationship between this application and the TRE presented earlier be further clarified. IGARD members were supportive of NHS Digital's assessment that COPI may be an option, but that using COPI notices would have limitations in that it is time bound and the applicant would therefore need a sunset clause or other exit mechanism. In addition, IGARD members discussed the sub-licencing and that the applicant would need a clear exit arrangement in place for any data onwardly shared. In terms of alignment with the existing consent materials, IGARD members suggested that NHS Digital review the applicant's suite of consent materials to ensure there was no definitive statement precluding sharing of data and explore if consent could be augmented by way of a newsletter to participants, including an additional paragraph as to how participants can withdraw their consent. Given the study outlined, length of time the applicant may wish to hold the data and that the applicant did not want to re-consent the cohort, IGARD members supported NHS Digital's assessment that the applicant may wish to explore s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG), but noted that HRA CAG would seek to clarify if the cohort could be re-consented. In addition, IGARD members noted that the applicant may wish to update their privacy notice(s) and remove any contradicting statements to what appears in the consent materials.
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.