Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 14 January 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Catherine Day	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS)
Kimberley Watson	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 and personal link to staff at the University of York [NIC-390749-C4P0X, NIC-06759-X5V7P and NIC-346859-C9J6J]. It was agreed this did not preclude Nicola from taking part in the discussions about these applications, however agreed that she would not participate in making a recommendation about the applications. Nicola Fear noted a personal link to staff at the University College London [NIC-384504-N2V5B]. It was agreed this did not preclude Nicola from taking part in the discussion about this

	application, however agreed that she would not participate in making a recommendation about the application. **Review of previous minutes and actions:** The minutes of the 17th December 2020 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	University of York: MR1126a - Yorkshire and Humberside Haematology Network (YHHN) (Presenter: Catherine Day) NIC-390749-C4P0X **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) data; and an amendment to 1) add Civil Registration, Cancer Registration and Demographics data to the Data Sharing Agreement, 2) to add Hull University Teaching Hospitals NHS Trust as a joint Data Controller. The purpose is to maintain and update the Yorkshire and Humberside Haematology Network's (YHHN) comparison cohort, and the overall aim is to facilitate a greater understanding of the causes of haematological cancers, as well as their impact on the future health and healthcare needs of those who develop them. This application is one of three linked applications, the others being NIC-06759-X5V7P (Item 2.2) and NIC-346859-C9J6J (Item 2.3), this application has a patient cohort for the study that was covered by consent. Application NIC-06759-X5V7P provides a national control cohort for the study and the patient cohort in application NIC-346859-C9J6J, is for those who were deemed too ill to provide consent and were covered by Section 251 of the NHS Act 2006. NHS Digital advised IGARD that within the application, there were references to *"supporting document 17"*, which was an amendment log for ethics approvals and consent forms, however confirmed that this document did not exist, and had been added in error, and that the references would need removing. NHS Digital also noted that the 'category' field in section 1 did not specify that the application was for an amendment **and** a renewal, and that this would be updated accordingly. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted the update from NHS Digital in respect of the incorrect references to *"supporting document 17"*, and supported the update to remove these references. IGARD also noted and supported the update to section 1, to reflect that the application was an amendment **and** a renewal. IGARD noted the amendment to the Data Sharing Agreement (DSA), to add Hull University Teaching Hospitals NHS Trust as a joint Data Controller, and queried if the Research Ethics Committee (REC) had been explicitly informed of this. NHS Digital advised that they were currently awaiting an update from the applicant on this query. IGARD noted the update and asked that if REC had not been notified, that the applicant should expressly notify REC that Hull University Teaching Hospitals NHS Trust was a joint Data Controller, and that a copy of any relevant documentation shared with NHS Digital in respect of this was uploaded onto NHS Digital's Customer Relationship Management (CRM) system.

	IGARD queried the role of Hull University Teaching Hospitals NHS Trust in light of information in section 5(b) (Processing Activities) that specifically stated that substantive staff of the Trust would be accessing the data; and asked that the application was updated throughout to provide a further explanation of the role and responsibilities of Hull University Teaching Hospitals NHS Trust as a joint Data Controller, including, but not limited updating the information in section 5(b). IGARD noted that the applicant's privacy notice had been updated to reflect that Hull University Teaching Hospitals NHS Trust were a joint Data Controller, and queried if the applicant was planning to also update the information leaflet to reflect this. NHS Digital advised that the applicant was in regular communication with the cohort, so did not anticipate any issue with this request. IGARD noted the update, and asked that in the next available communication to the cohort, and in line with the obligations set out in Article 26(2) of the UK General Data Protection Regulation (GDPR). IGARD suggested that the applicant informed the existing cohort that Hull University Teaching Hospitals NHS Trust was a joint Data Controller, and that this communication was completed no later than 12 months after the receipt of data under this DSA. Accordingly, IGARD asked that a special condition was inserted in section 6 (Special Conditions) that the applicant would update the existing cohort within 12 months of receipt of the data. IGARD also asked that **all** patient-facing materials going forward, for example the patient information sheet, were updated to correctly reference that Hull University Teaching Hospitals NHS Trust were a joint Data Controller. IGARD noted the cohort figure differed throughout the application (18,000 versus 15,000), and asked that the application was updated throughout to ensure the correct cohort figure was stated; and that if there was a discrepancy with the numbers, that for clarity, a further explanation was provided confirming why. IGARD had a lengthy discussion on patient objections, and queried if the information in section 3(c) (Patient Objections) that stated patient objections were being applied was correct, since this application is for a consented cohort. IGARD advised that patient objections do not need to be applied for the consented cohort, and asked that section 3(c) was updated to remove the reference to patient objections being applied; or, asked that if patient objections would continue to be applied, that a brief explanation was applied in section 3(c) to confirm why. IGARD suggested that in the in the next communication with the cohort, if applicable, the applicant may wish to advise that the National Data Opt-out was being upheld and to provide a brief explanation confirming why. IGARD noted and commended the inclusion of details in section 5(c) (Specific Outputs Expected), in relation to those cohort members who had elected not to have their data sent to NHS Digital for linkage; however, suggested that for transparency this was moved to section 5(a) (Objective for Processing). IGARD noted the information in section 5(c), that all the reports from the study would be open access publications, and commended the applicant for adopting this approach. IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and in light of the large-scale project, queried if this was correct, for example, was the data being backed-up to a different storage location; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) if appropriate.

	IGARD suggested that the statement in section 5(a) that stated *"…there are no moral or ethical issues…"* was removed since it was not necessary to include in the application. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of Hull University Teaching Hospitals NHS Trust: a) The applicant to expressly notify REC that Hull University Teaching Hospitals NHS Trust is a joint Data Controller. b) To provide a copy of any relevant documentation to NHS Digital for uploading onto NHS Digital's CRM system. The following amendments were requested: 1. In respect of Hull University Teaching Hospitals NHS Trust: a) To update the application throughout, to provide a further explanation of the role and responsibilities of Hull University Teaching Hospitals NHS Trust as a joint Data Controller, including (but not limited to) section 5(b), which specifically refers to them accessing the data. b) In the next available communications, to inform the existing cohort, that Hull University Teaching Hospitals NHS Trust is a joint Data Controller, (and no later than 12 months after the receipt of data under this DSA). c) To insert a special condition in section 6 that the applicant will update the existing cohort, within 12 months of receipt of the data. d) To update all patient-facing materials going forward (for example the patient information sheet), to correctly reference that Hull University Teaching Hospitals NHS Trust are a joint Data Controller. 2. To update the application to ensure the correct cohort figure is stated consistently throughout (and if there is a discrepancy to explain why this is). 3. In respect of the patient objections: a) To update section 3(c) to remove the reference to patient objections being applied, or: b) If patient objections are applied, to include a brief explanation in section 3(c) to confirm why. c) To update section 3c, depending on whether the patient objections are being applied, to align the wording with the option selected above. 4. To clarify if there are any additional storage locations and to amend section 2(b) if appropriate. 5. To remove from section 5(a) reference to '*there are no moral or ethical issues*". 6. To move the wording, where cohort members elected not to send their data to NHS Digital, from section 5(c) to section 5(a). The following advice was given: 1. IGARD suggested that in the next communication with the cohort, if applicable, the applicant may wish to advise that the NDO is being upheld and to provide a brief explanation confirming why. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
2.2	<u>University of York: MR1325 - Yorkshire and Humberside Haematology Network Register (YHHN) Comparison Cohort (Presenter: Catherine Day) NIC-06759-X5V7P</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) data; and an amendment to 1) add Civil Registration, Cancer Registration and Demographics

	data to the Data Sharing Agreement, 2) to add Hull University Teaching Hospitals NHS Trust as a joint Data Controller. The purpose is to maintain and update the Yorkshire and Humberside Haematology Network's (YHHN) comparison cohort, and the overall aim is to facilitate a greater understanding of the causes of haematological cancers, as well as their impact on the future health and healthcare needs of those who develop them. This application is one of three linked applications, the others being NIC-390749-C4P0X (Item 2.1) and NIC-346859-C9J6J (Item 2.3), this application provides a national control cohort for the study. The patient cohort in application NIC-390749-C4P0X is covered by consent and the patient cohort in application NIC-346859-C9J6J, is for those who were deemed too ill to provide consent and were covered by Section 251 of the NHS Act 2006. NHS Digital noted that the 'category' field in section 1 did not specify that the application was for an amendment **and** a renewal, and that this would be updated accordingly. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted and supported the update from NHS Digital in respect of updating section 1, to reflect that the application was an amendment **and** a renewal. IGARD noted that in supporting document 7.2, the Health Research Authority Confidentiality Advisory Committee (HRA CAG) correspondence dated the 25th August 2020, that HRA CAG had advised it would consider an updated application on the 19th November 2020. IGARD advised that they had not received an update of this review (including whether it had taken place), and therefore asked that evidence was provided of the unconditional HRA CAG support, including all relevant application documentation. In addition, NHS Digital should be assured that the unconditional HRA CAG support aligned with the proposed processing set out in this application. IGARD had a lengthy discussion on patient objections, and queried if the information in section 3(c) (Patient Objections) that stated patient objections were being applied was correct. IGARD asked that section 3(c) was updated with a brief explanation of the approach taken to objections. IGARD suggested if the HRA CAG application was still in progress, and had not been submitted by the applicant for review, the applicant may wish to consider making specific representation to the committee in respect of the National Data Opt-out. In addition, IGARD asked that the National Data Opt-out query be addressed to IGARD's satisfaction, and amendments made as appropriate to the application. IGARD queried the Patient Information Advisory Group statement in section 1 (Abstract), that stated the *"…data for the comparison cohort will be anonymised before being released…"*, and asked that this was removed as it was dated language that did not reflect the pseudonymised nature of the data flowing. IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and in light of the large-scale project, queried if this was correct, for example, was the data being backed-up to a different storage location; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) if appropriate. IGARD queried the statement in section 5(b) (Processing Activities) that stated: *"Data for the comparison cohort is pseudonymised and does not contain any personal or sensitive fields.",* and asked that this was removed as it was incorrect and did not align with information provided elsewhere in the application that stated there were sensitive fields. **Outcome:** recommendation to approve subject to the following condition:

	1. In respect of HRA CAG: a) To provide evidence of unconditional HRA CAG support, including all relevant application documentation. b) That the unconditional HRA CAG support aligns with the proposed processing set out in this application. c) That the NDO questions have been addressed to IGARD's satisfaction, and amendments made as appropriate to the application. The following amendments were requested: 1. To remove from section 1 the direct quote from the PIAG documentation referring to *"anonymised"* data. 2. To clarify if there are any additional storage locations and to amend section 2(b) if appropriate. 3. To update section 3, as may be necessary, with regard to NDO following the HRA CAG review (links to condition 1(c)). 4. To update section 5(b) to remove the reference to *"no sensitive fields"*. The following advice was given: 1. IGARD suggested if the HRA CAG application is still in progress, to consider making specific representation to the committee in respect of the NDO. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.3	University of York: MR1126b - Yorkshire and Humberside Haematology Network (YHHN) (Presenter: Catherine Day) NIC-346859-C9J6J **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) data; and an amendment to 1) add Civil Registration, Cancer Registration and Demographics data to the Data Sharing Agreement, 2) to add Hull University Teaching Hospitals NHS Trust as a joint Data Controller. The purpose is to maintain and update the Yorkshire and Humberside Haematology Network's (YHHN) comparison cohort, and the overall aim is to facilitate a greater understanding of the causes of haematological cancers, as well as their impact on the future health and healthcare needs of those who develop them. This application is one of three linked applications, the others being NIC-390749-C4P0X (Item 2.1) and NIC-06759-X5V7P (Item 2.2) and that this application was for the patient cohort too ill to provide consent and were therefore covered by Section 251 of the NHS Act 2006. Application NIC-06759-X5V7P provides a national control cohort for the study and NIC-390749-C4P0X had a patient cohort for the study that was covered by consent. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted that in supporting document 7.2, the Health Research Authority Confidentiality Advisory Committee (HRA CAG) correspondence dated the 25th August 2020, that HRA CAG had advised it would consider an updated application on the 19th November 2020. IGARD advised that they had not received an update of this review (including whether it had taken place), and therefore asked that evidence was provided of the unconditional HRA CAG support, including all relevant application documentation. In addition, NHS Digital should be assured that the unconditional HRA CAG support aligned with the proposed processing set out in this application. IGARD suggested if the HRA CAG application was still in progress and had not been submitted by the applicant for review, the applicant may wish to consider making specific

	representation to the committee in respect of the National Data Opt-out with regard to the three linked applications. IGARD queried reference to *"…sex and gender..."* in section 5(a) (Objective for Processing), and asked that the datasets requested in the application aligned with the specific NHS Digital data that can flow, for example requesting 'sex' rather than 'gender' if "sex" is what is captured in the dataset. IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and in light of the large-scale project, queried if this was correct, for example, was the data being backed-up to a different storage location; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) if appropriate. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of HRA CAG: a) To provide evidence of unconditional HRA CAG support, including all relevant application documentation. b) That the unconditional HRA CAG support aligns with the proposed processing set out in this application. c) That the NDO questions have been addressed to IGARD's satisfaction, and amendments made as appropriate to the application. The following amendments were requested: 1. To ensure that the datasets requested align with the specific NHS Digital data that can flow, for example requesting 'sex' rather than 'gender' if "sex" is what is captured in the dataset. 2. To clarify if there are any additional storage locations and to amend section 2(b) if appropriate. The following advice was given: 1. IGARD suggested if the HRA CAG application is still in progress, to consider making specific representation to the committee in respect of the NDO. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.4	<u>University College London: Centre for Longitudinal Studies - Millennium Cohort Study (MCS)- (Age 17 consent) (Presenter: Catherine Day) NIC-384504-N2V5B</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS). The Centre for Longitudinal Studies (CLS) at University College London (UCL) is an academic resource centre responsible for producing and disseminating data resources for the scientific community. It is responsible for four of Britain's internationally renowned Longitudinal Cohort Studies, 1) the 1958 National Child Development Study, 2) the 1970 British Cohort Study, 3) the Next Steps, and 4) the Millennium Cohort Study (MCS). All four studies are following the groups of participants from cradle to grave, and is providing a wealth of information used in the policy decisions affecting society's health and well-being. The purpose of this application covers two aspects: a) Request linkage of HES and ECDS data to a subset of the MCS (only cohort members who consented to have their health records linked to their survey data), and b) CLS is seeking permission to sub-licence this linked data with the research community via the UK Data Service (UKDS).

	Discussion: IGARD members had reviewed the consent materials provided and noted that on balance the consent allowed for sub-licencing. In addition IGARD noted the excellent approach taken to the sub-licencing review had mapped to the NHS Digital DARS Standard for sub-licencing. IGARD queried, noting the length of time the study had been running, the applicant held any other NHS Digital data for the cohort in this application, for example under a different NIC number, and asked that confirmation was provided; and if so, to update section 1 (Abstract) with the relevant NIC number for future reference. IGARD noted that section 2(b) (Storage Location(s)) only listed two storage locations, and in light of the large-scale project, queried if this was correct, for example, was the data being backed-up to a different storage location; and asked that clarification was provided if there were any additional storage locations or safe havens and to amend section 2(b) if appropriate. IGARD noted that a number of yielded benefits had been listed in section 5(d) (Benefits) that specifically accrued to health and social care, however queried the relevance of the academic reference outputs also listed, and suggested that these were removed. IGARD noted the information in section 5 (Purpose / Methods / Outputs) that referred to Public Task as a UK General Data Protection Regulation (GDPR) legal basis, and asked that the Terms of Reference (ToR) for the sub-licence scheme was updated to align with section 5, and to specify that sub-licensees must have Public Task as a UK GDPR legal basis. IGARD suggested that for future renewals, that the applicant either maintained the study protocol, or furnish any internal guidance documents that may be relevant, so that a review can be carried out as to how the proposed processing aligned with the stated research goals. **Outcome:** recommendation to approve The following amendments were requested: 1. To clarify if there are any additional storage locations or safe havens and to amend section 2(b) if appropriate. 2. To provide confirmation that the applicant does not hold any other NHS Digital data for this cohort, for example under a different NIC number; and if so, to include the NIC number in section 1. 3. To update section 5(d) to ensure that the yielded benefits just reflect those benefits accruing to Health and Social Care and to remove the academic reference outputs. 4. To update the ToR for the sub-licence scheme, to specify that sub-licensees must have Public Task as a GDPR legal basis to align with the narrative in section 5. The following advice was given: 1. For future renewals, IGARD suggested that the applicant either maintain the study protocol or furnish any internal guidance documents that may be relevant so that a review can be carried out as to how the proposed processing aligns with the stated research goals.
2.5	<u>Royal National Orthopaedic Hospital (RNOH) NHS Trust: Royal National Orthopaedic Hospital and Edge Health delivering service improvement for the NHS, including the Getting It Right First Time programme (Presenter: Denise Pine) NIC-14440-Q2G4W</u> **Application:** This was a renewal and extension application for pseudonymised Hospital Episode Statistics (HES) data; and an amendment to 1) update the purpose to: a) to extend

	the Get It Right First Time (GIRFT) programme beyond the current workstreams to cover: paediatric surgery, cancer services, rehabilitation, wound care, prison health, alongside other areas that are yet to be identified, b) to extend the GIRFT work on a commercial basis. C) to extend permission previously granted to share small volume activity data products produced using the data in this application; and 2) to remove Neil Wilson Associates LLP as a Data Processor. The purpose is to support the GIRFT programme, which is a large national programme with the aim of supporting NHS organisations to improve services, principally to improve clinical quality, delivery productivity and patient experience of care. NHS Digital advised IGARD that the application stated there were 43 workstreams, however advised that this would incorrect and would need updating to correctly state 35 workstreams. NHS Digital noted that the International Organization for Standardization (ISO) for Edge Health Ltd had expired, and advised that the applicant had provided an updated certificate of assurance, and that this would need reviewing by NHS Digital's Security Manager. **Discussion:** IGARD noted the update from NHS Digital in respect of the incorrect reference to the 43 workstreams, and supported the update to update this reference to reflect 35 workstreams. IGARD also noted the update in respect of the ISO certification for Edge Health Ltd. IGARD suggested that legitimate Interests would be the appropriate legal gateway to rely upon under the UK General Data Protection Regulation (GDPR) for the processing under the commercial arm of the program and. If the applicant did not agree, IGARD suggested they provide a clear justification, for example by reference to the Information Commissioner's Office (ICO) guidance for universities, as to why the commercial element of the processing was not carried out under Legitimate Interests. IGARD noted that any application citing two legal bases should clearly articulate which tasks were being undertaken under which legal basis, for instance the tasks undertaken under Legitimate Interest and the tasks undertaken under Public Task. In addition, IGARD also asked that section 5(a) (Objective for Processing) was updated, and throughout the application as may be required, to ensure that reference to the specific Legitimate Interests as linked to the processing as per NHS Digital's DARS Objective for Processing Standard. IGARD queried if the GIRFT funding explicitly permitted, or that specific permission has been granted by the funder: (i) for the commercial arm activities; and (ii) that the profits from such activities were being directed solely back into the RNOH. IGARD asked that confirmation of such permissions was provided. IGARD queried if the applicant was receiving enough data to be able to achieve their research objectives, for example, the proposed projects in wound care and rehabilitation; and asked that confirmation that the proposed processing and outputs can be achieved with the limited inpatient datasets requested. IGARD suggested that in order to achieve the stated outputs and benefits, and to ensure that those outputs were robust and to minimise the risk of misleading results, further NHS Digital data may be required, for example outpatient datasets. IGARD queried if the applicant received other datasets, for example, colonoscopy data, and asked that confirmation was provided; and in addition, asked that confirmation was provided confirming that the NHS Digital was not being linked with any other data.

	IGARD noted this was the first application they had seen that took the novel approach of using public money to monetise aspects of the research outputs and funnel the money made back into a geographically restricted area/subset of patients-. IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold and process the data while work was undertaken to address the queries raised by IGARD. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; and that, in addition, save for the short-term extension suggested, IGARD also suggested that this application would not be suitable for NHS Digital's Precedent route. **Outcome:** Recommendation to defer, pending: 1. In respect of the commercial element of the processing: a) To state that the commercial element of processing would be carried out under Legitimate Interests or provide a clear justification (for example by reference to ICO guidance) as to why the commercial element of the processing is not carried out under Legitimate Interests. b) To update section 5(a) and throughout the application, as may be required, to ensure reference to the specific Legitimate Interests as linked to the processing as per NHS Digital's DARS Objective for Processing Standard. 2. To confirm that all of the proposed processing and outputs can be achieved with the limited inpatient datasets requested, for example, the proposed projects in wound care and rehabilitation. 3. In respect of the data requested: a) To confirm that there are no other datasets received by the applicant. b) To confirm that the NHS Digital data is not being linked with any other data. 4. In respect of the funding, to confirm that the GIRFT funding explicitly permits, or that specific permission has been granted by the funder for: a) the commercial arm activities; and b) the profits from such activities being directed solely back into the RNOH. The following advice was given: 1. IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold and process the data while work was undertaken to address the queries raised by IGARD. 2. IGARD suggested that in order to achieve the stated outputs and benefits, and to ensure that those outputs were robust and to minimise the risk of misleading results, further NHS Digital data may be required, for example outpatient datasets. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 4. Save for the short-term extension suggested in advice point 1 above, IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.6	Nottingham University Hospitals NHS Trust: MR1469 - Demographic, morbidity and mortality data associated with the STOP-HCV Cirrhosis Study cohort. (Presenter: Denise Pine) NIC-72626-V4P9B **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES), Medical Research Information Service (MRIS) and Diagnostic Imaging Dataset (DID);

	and an amendment to 1) request an annual disseminations of all HES products (with the exception of HES AE, which has been replaced by ECDS) and DID (linked via a bridge field), alongside the newly requested Civil Registry, Cancer Registration and Demographic data, 2) request a re-supply of data previously disseminated for a different cohort consisting of around 3,300 individuals, 3) to request annual disseminations of all datasets previously received for both cohorts, 4) to update section 5a and 5b to reflect the receipt of data for the new cohort, 5) to update section 5c to adjust the expected target dates of outputs, and 6) to update section 5d to detail newly generated benefits. The purpose is for a research study on Hepatitis C Virus (HCV) cirrhosis of the liver, which is a sub-study of HCV Research UK (HCVRUK). This application seeks to extend the numbers of patients with HCV-associated cirrhosis from the original 1264 co-enrolled within the STOP-HCV Cirrhosis study to include all cirrhotic patients within HCV Research UK (i.e. irrespective of whether or not each patient was co-enrolled within STOP-HCV). The enhanced patient numbers will increase both the number of critical clinical endpoints achieved (decompensation of liver disease, diagnosis of hepatocellular carcinoma) and this in turn will increase the number of variables that can be analysed for their value in predicting the development of complications of cirrhosis. **Discussion:** IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and in light of the large-scale study, queried if this was correct, for example, was the data being backed-up to a different storage location; and asked that clarification was provided if there were any additional storage locations or safe havens and to amend section 2(b) if appropriate. IGARD queried the reference in section 5(a) (Objective for Processing) to *"Asckey Data Services Ltd",* and noting that they were not referred to elsewhere in the application, asked that section 5(a) was updated to clearly describe the activities they carried out. IGARD noted the statement in section 5(a) that *"Researchers may apply to the HCVRUK Tissue and Data Access Committee (TDAC) for access to data…"*, and queried if the data that was considered by the Committee included NHS Digital data; and were advised by NHS Digital that it did not. IGARD noted the update from NHS Digital and asked that section 5(a) was updated clarifying that the TDA Committee did not consider applications for NHS Digital data. IGARD noted the paragraph included for the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally. IGARD queried the statement in section 5(d) *"…chronic HCV is estimated to affect approximately 0.5% to 1% of the population…",* and advised that it appeared to be quite high, and different from other (lower) figures stated elsewhere; and asked that the stated prevalence figures were reviewed, and to the extent that the work carried in the study may be contributing to the decrease in prevalence and to highlight this. IGARD noted in section 1 (Abstract) that the study is still actively recruiting patients, and asked that this was updated to confirm that whilst they are still recruiting, they will **not** be adding to the cohort figure. IGARD suggested that if the cohort members are added to, at any point in the future, that the consent materials were revised as suggested by IGARD in 2019, namely, to refer to the flow of identifiers to NHS Digital.

	Outcome: recommendation to approve The following amendments were requested: 1. To clarify if there are any additional storage locations or safe havens and to amend section 2(b) if appropriate. 2. To update section 5(a) to describe the activities carried out by Asckey Data Services Ltd. 3. To update section 5(a) to explain that the TDA Committee does not consider applications for NHS Digital data. 4. To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally. 5. To review the stated prevalence figures in section 5(d) and to the extent of the work carried in the study may be contributing to the decrease in prevalence and to highlight this. 6. To update section 1 to clarify that while they are still recruiting, they will not be adding to the cohort figure. The following advice was given: 1. IGARD suggested that if the cohort members are added to, at any point in the future, that the consent materials are revised as suggested by IGARD in 2019, namely, to refer to the flow of identifiers to NHS Digital.
2.7	Ignite Data Limited: The Extended Salford Lung Study Data Access Project (Presenter: Kimberley Watson) NIC-115298-L5X4V **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data, for the purpose of a follow-on study. The Extended-Salford Lung Study is a follow-on study to the original Salford Lung Studies (SLS), two landmark effectiveness trials of fluticasone furoate / vilanterol (an inhaled corticosteroid combined with a long-acting-b2-agonist [LABA] in a single inhaler device) in patients with Chronic Obstructive Pulmonary Disease (COPD) and asthma which ran from March 2012 to December 2016. The data will be used to form a longitudinal patient record, over the lifetime of the study, and will answer questions in the Extended-SLS relating to, 1) Healthcare resource utilisation and costs (HRG); 2) Severe exacerbation's of COPD and asthma; 3) Frailty and disease severity defined based on prior hospitalisations (all-cause) and comorbidities not managed in primary care. 4) Potential, treatment-related adverse events resulting in hospitalisation; 5) the impact of treatments and / or disease severity / subtypes on all-cause or COPD- and asthma- related mortality; primary care. NHS Digital noted that the application stated the original studies ran from 2016 – 2020, however advised that this was an error, and would need amending to reflect that the studies ran from 2012 – 2016. NHS Digital advised that versions 2.0 and 2.1 of the consent materials were originally used to consent 62 patients, however the materials did not meet reasonable expectations, and the 62 patients were therefore not part of the cohort referred to within the application; and that the cohort included, were recruited with version 3 of the consent materials.

	Discussion: IGARD noted the update from NHS Digital in respect of the study years for the original studies, and supported the updated to the application. IGARD also noted the cohort recruitment history and the versions of the consent materials used for this application. IGARD's view was that the consent materials were consistent with the processing outlined in the application as the application only requested 10 years of data; however, should the applicant wish to request further data from NHS Digital in subsequent years, IGARD suggested that the applicant clarify with the consented cohort, by way of a newsletter update, that the 10 years of data referred to in the consent materials referred to the data flowing from the date of consent and that historical data was also being requested from NHS Digital. IGARD noted that the data minimisation column in section 3(b) (Additional Data Access Requested) was inconsistent with the rest of the application, in respect of the 10 years of data that had been requested, and asked that this was amended accordingly. IGARD queried which GlaxoSmithKline (GSK) company were contracting with NHS Digital, noting that this was not explicitly clear, and asked that section 1 (Abstract) was updated clarifying this point. Noting that GSK is an international pharmaceutical company, IGARD advised that this should be clear within the public facing section 5 (Purpose / Methods / Outputs) for transparency, and to also clarify that the relevant GSK company registered in England and Wales was the contracting party, if applicable. In addition, IGARD also asked that a special condition was inserted in section 6 (Special Conditions), that any reference to *"GSK handling data"* was referring to the relevant GSK company registered in England and Wales. IGARD also noted that GSK was a pharmaceutical company that produced drugs directly relevant to the ailments being studied and outlined in this application, and held the international patent to one of the drugs specifically referred to in the application; and asked that this was made explicitly clear in section 5(a) (Objective for Processing). In addition, IGARD also asked that it was made make in section 5(e) (Is the purpose commercial?) that GSK is a pharmaceutical company making drugs in the respiratory domain and that this may have benefits further to what is outlined in the application, such as increased market share or development of new drugs. IGARD noted that Legitimate Interests were being relied upon under the UK General Data Protection Regulation (GDPR) by GSK, and therefore asked that section 5(a) was updated, and throughout the application as may be required, to ensure that any references to the specific Legitimate Interests was linked to the processing and expected measurable benefits, as per NHS Digital's DARS Objective for Processing Standard. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section1 to reflect that the original study ran from 2012 – 2016. 2. To amend the data minimisation column in section 3(b) to reflect the 10 years of data requested. 3. In respect of GSK:

	a) To update section 1 to be clear which GSK company is contracting with NHS Digital. b) To be clear in section 5 that GSK is an international pharmaceutical company, and the relevant GSK party is a company registered in England and Wales. c) To insert a special condition that any reference to "GSK handling data" is referring to the relevant GSK company registered in England and Wales. d) To be explicitly clear in section 5(a) that GSK is a pharmaceutical company that produces drugs directly relevant to the ailments being studied and holds the international patent to one of the drugs specifically referred to in the application. e) To update section 5(e) to make clear that GSK is a pharmaceutical company making drugs in the respiratory domain and may have benefits further to what is outlined in the application, such as increased market share or development of new drugs. f) Noting GSK is relying on Legitimate Interests, to update section 5(a) and throughout the application, as may be required, to ensure reference to the specific Legitimate Interests is linked to the processing and expected measurable benefits, as per NHS Digital's DARS Objective for Processing Standard. The following advice was given: 1. IGARD's view is that the consent materials were consistent with the processing outlined in the application; however, should the applicant wish to request further data from NHS Digital, IGARD suggested that the applicant clarify with the consented cohort, by way of a newsletter update, that the 10 years of data referred to in the consent materials referred to the data flowing from the date of consent and that historical data was also being requested from NHS Digital. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
	<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.
4	<u>IG Covid-19 Release Register October - November 2020</u> IGARD noted that the IG Covid-19 Release Register October - November 2020 had been circulated and reviewed out of committee by members, and discussed and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate. In addition, IGARD agreed that NHS Digital's Caldicott Guardian should be invited to attend future IGARD meetings where the IG Covid-19 Release Register is discussed, to observe and participate in the discussion.
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 Thursday 7th January and Tuesday 12th January 2021 can be found attached to these minutes as Appendix B.
6	AOB:
6.1	NIC-173508-F4X6P – Isle of Man Department of Health & Social Care IGARD noted that as part of their review of NIC-173508-F4X6P, the Isle of Man Department of Health & Social Care application on the 13th August 2020, 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. NHS Digital advised IGARD via e-mail on the 18th December 2020, that a short 3-month renewal under SIRO had been put in place, and confirmed that this would be returning for a further IGARD review in early 2021. IGARD noted and thanked NHS Digital for providing an update and acknowledged the forthcoming review of the application at a future IGARD meeting.
6.2	IGARD Meeting Quoracy In light of the ongoing situation with COVID-19, and following consideration by IGARD members, it has been agreed with NHS Digital that from the 26th March 2020 meeting, the in-meeting quoracy may be temporarily reduced to three members (from four members), which must include a Chair and at least two specialist members. This is to ensure business continuity in the event that Covid-19 impacts on members ability to dial-in to meetings (due to illness or caring for a household member) and to support those IGARD members who have other roles linked to the Covid-19 response. This will be reviewed as and when required, but no less than monthly, and in response to new guidance that is released. This relates to Covid-19 only. 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 11/12/20

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-365602-V5H3Z	King's College London	19/11/2020	1. In respect of the date of death (noting NHS Digital policy): a) To provide a rationale as to why the date of death is considered not to be owed a duty of confidence given the other data sets involved and the context within which this data sits. b) To provide a statement in section 1 asserting that, in light of an assessment of the fact, the data is not owed a duty of confidence.	IGARD members	Quorum of IGARD members	None
NIC-327960-M2P9M	Swansea University	26/11/2020	2. In respect of the references to "presumed consent", to update section 5 throughout: a) To remove all references to *"presumed consent"*. b) To replace with a clear explanation of how the cohort members are selected and identified. c) To also include the legal basis for following and processing the cohort's health information (for example by reference to the s251 support).	IGARD members	Quorum of IGARD members	In respect of amendment 5, IGARD noted: There is one more reference to aggregate data in Section 5: *"Study outputs will present aggregate data only; small groups will be merged where possible and meaningful."* IGARD suggested adding a further query about the study output small numbers being supressed *"where possible"*

						and would check this aligns with permissions and policy.

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

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Thursday, 7th January 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Maurice Smith (IGARD Specialist GP Member)
In attendance (NHS Digital):	Andrew Clayton (Data Architecture & Secondary Use Transformation – Observer)
	Duncan Easton (DARS)
	Karen Myers (IGARD Secretariat)
	Stuart Richardson (Data Architecture & Secondary Use Transformation)
	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:** There were no declarations of interest.
2.1	Briefing Paper – Ambulance Data Set (ADS) Pilot **Background:** this was a business as usual (BAU) briefing paper which outlined the ADS pilot being led by NHS England and NHS Improvement who have commissioned NHS Digital to develop a dataset via a work package under a Provision of Services Agreement (POSA). The pilot is to implement the processing of emergency and urgent care related data collected by English Ambulances Services to NHS Digital with key operational data items in "*near real-time*" and other key data items to be linked to the Emergency Care Dataset (ECDS). A two stage approach has been developed to pilot operational (Computer Aided Despatch – CAD) and then clinical data (Electronic Patient Record – EPR) collection and transfer. The project will produce interim and full impact assessments and options appraisals on both the operational and clinical components. A successful pilot will result in a data set that produces "*dashboard*" type operational information available in 15-minute intervals from data receipt. The direction is limited in scope to the pilot activity and as such is known as a "discovery Direction"

	IGARD Observations: IGARD members noted this was a BAU briefing paper and noted that due to the quick turn-around, quoracy and nature of this COVID-19 response meeting, they were not able to undertake a BAU formal review, however, they made the following observations on the briefing paper: • Where referencing Data Controllership, to update the briefing paper to be clear who may receive the data and to align with the specific named recipients set out in the 2nd November discovery Direction (the "Permitted Recipients"). • Where the briefing paper discusses providing "*publishable data*" to the Project Board, to consider changing the wording to aggregated data with small numbers suppressed, since NHS Digital is directed not to publish any information. • With reference to the General Data Protection Regulation (GDPR) Article 9 legal bases cited in the briefing paper, to: o Cite just the one Article 9 legal basis, since two are currently listed, or o If relying on the two Article 9 legal bases to be clear which activities relate to which Article 9 legal basis; and o if relying on substantial public interest (Article 9(2)(g)), to clearly set out the analysis of why this is being relied upon and to specify the relevant substantial public interest condition paragraph nominated under Schedule 1 Data Protection Act (DPA) 2018. IGARD members also provided the following observational advice: • IGARD members suggested that NHS England and the 11 English Ambulance Services consider how this new project could be factored into their existing transparency initiatives, and in line with the new Caldicott Principle 8. • IGARD suggested that NHS England, once this had moved from the pilot stage, consider ensuring that the future Direction(s): o allow for researchers and other potentially relevant bodies to access the data; o refer to NHS England carrying out linkage and any other desired activities, noting that the current Direction only permits NHS Digital to carry out data linkage. In summary, IGARD members noted that they were supportive of the new data collection and draft briefing note and offered additional support to NHS Digital by way of circulating the updated briefing note out of committee in order to help expedite progress. IGARD members noted that the finalised briefing note would be received at a future BAU meeting for transparency of process and to be noted in the published minutes.
2.2	<u>NIC-139035-X4B7K NHS England (Quarry House)</u> **Background:** This was a business as usual (BAU) application that had been brought for a formal review and recommendation on the following amendments;

	a) addition of joint Data Controllers Monitor and the Trust Development Agency (TDA) representing the legal entities comprising NHS Improvement,
	
	b) the addition of OBH as a Data Processor processing record level pseudonymised NCDR data to develop a population health management segmentation model.
	
	c) the addition of the following datasets: Summary Hospital-level Mortality Indicator (SHMI) data, 111 Pathways data, Medicines Prescribed in Primary Care data and Ambulance Data Set (ADS), and
	
	d) the addition of ANS Group Limited an organisation that is assisting in the set up and management of South, Central and West Commissioning Support Unit (CSU) Microsoft Azure Cloud.
	
	This NIC number has been previously discussed at IGARD BAU meetings on the 17th December, 17th November, 9th July and 13th February 2020, 12th December, 17th October, 15th August, 25 April 2019, however the last time the overarching commissioning application had been presented had been at the IGARD BAU meeting on the 9th July 2020.
	
	IGARD Observations:
	
	IGARD members noted that due to the quick turn-around of papers, quoracy and nature of this COVID-19 response meeting, they were not able to undertake a BAU formal review and recommendation on the application. IGARD noted the update from NHS Digital and discussed the breadth and scope of this complex application and advised NHS Digital that they would be focussing only on the amendments highlighted.
	
	IGARD members noted that that the application and relevant supporting documents would be presented to a future BAU meeting, and, noting that the discussion today was not to pre-empt discussions that would take place at a future BAU meeting, IGARD suggested that DARS ensure the application was updated to reflect the following key points:
	
	• Since the ADS data is a pilot scheme (as outlined in the briefing paper) and has limitations as set out in the 2nd November discovery Direction, that this ADS data request be either:
	  ○ Ringfenced as a separate “application” within this main overarching commissioning application to clearly delineate it from all other datasets, processing and linkage, and to ensure it remains within the scope of the discovery Direction (for example removing reference to “linkage”, since this is undertaken by NHS Digital (as set out in paragraph 4 of the discovery Direction)), or
	  ○ Hived off into a brief time-limited application, reflecting the parameters of the discovery Direction and Briefing Paper, for the bespoke ADS pilot. IGARD would be supportive of the SIRO considering such a bespoke application under the SIRO precedent.
	• With reference to the other amendments to the application:
	  • Noting the inclusion of NHS Improvement, via Monitor and TDA as joint Data Controllers, to the application, to confirm there are no restrictions in any Directions underpinning the various datasets as to receipt or controllership of the data.
	  • Further detail should be included in section 5 of the publicly available application with regard to OBH (Data Processor) for transparency, for example who they are and if the work they are untaken is paid.

	• To update section 5 to provide further justification for the inclusion of the Summary Hospital-level Mortality Indicator (SHMI) data and how this relates to commissioning, since this data is usually used to help to assess healthcare outcomes and patient safety, and identify poor performance with consequent opportunity for quality improvement. • Noting the Medicines Prescribed in Primary Care data is a vast dataset containing all patient level prescriptions, and its Direction is very specific, to update the application with the previously provided advice from NHS Digital's Privacy, Transparency and Ethics (PTE) Directorate (formerly Information Governance Directorate) with regard to the scope of the processing mapped against the Direction and the agreed wording relating to processing - as per NIC-403394 class action application for 135 CCGs. (The application currently refers to the data being needed for "*pandemic research and planning*" and spotting medicine shortages, however the NHSBSA Direction states that the purpose of the Direction is to "*provide intelligence about the safety and effectiveness of medicines*". The proposed processing must be aligned to the legal gateway.) • IGARD suggested that NHS Digital liaise with their Data Security and Protection Toolkit (DSPT) Team in relation to NHS Improvement's current DSPT and whether extra protection is required, in light of on-going organisational changes. • IGARD reiterated their previous comments from the 9th July that the yielded benefits should be updated in accordance with NHS Digital's published Standard 5d • IGARD reiterated their previous action point that: NHS Digital convene a working group to review the process of assuring and onboarding of the additional datasets. IGARD suggested that they would wish to review this overarching commissioning 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.
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.

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 12th January 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	Garry Coleman (DARS – observer item 2.3)
	Louise Dunn (DARS)
	Mujiba Ejaz (DARS – Observer items 2.1-2.3)
	James Gray (DARS)
	Karen Myers (IGARD Secretariat)
	Andy Rees (DARS)
	Vicki Williams (IGARD Secretariat)

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 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:** Geoff Schrecker noted a previous working relationship with some staff involved with NIC-382794-T3L3M University of Oxford application when he was a member of the QResearch Advisory Board. It was agreed this did not represent a substantive conflict of interest.
2.1	<u>Permission to Contact (No NIC number available)</u> **Background:** This a verbal briefing with regard to a draft vaccine registry application looking at flexibility across the immunisation programme in relation to 1 prime jab and 1 booster jab of a vaccine, for a cohort of approximately 460 people, aged 50 years plus with no underlying health concerns. NHS Digital noted that no documentation or application was available for review by IGARD members. NHS Digital noted that Permission to Contact (PtC) had been discussed a number of times at both the IGARD business as usual meetings and COVID-19 response meetings.

	NHS Digital noted that this was an urgent application and would likely be proceeding via the NHS Digital DARS SIRO Precedent route due to the urgency, but had been brought to IGARD for advice. The following observations were made on the basis of the verbal briefing only. **IGARD Observations:** IGARD noted that there were a number of issues and queries for the Ethics Committee to consider and that these were outside the scope of IGARD's remit, including, but not limited to; the size of the cohort, whether researchers (cf the NHS) contacting citizens directly was best practice, and the interplay of this trial with the simultaneous national vaccine roll out. Noting that the consent materials were not under review, IGARD members notwithstanding took the opportunity to suggest that the applicant ensure that the consent materials did not limit any future research, including linkage or follow up. IGARD members welcomed the verbal update from NHS Digital with regard to a proposed application, and confirmed that they were supportive of this application going via the NHS Digital DARS SIRO Precedent, but noted that they would welcome an update on the draft application at a future COVID-19 response meeting or the COVID-19 update section of a BAU meeting.
2.2	<u>NIC-386685-K2B6G Royal Free London NHS Foundation Trust</u> **Background:** This was a draft application for the request for Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) data for the FLARE Trial. The purpose of the application is to identify individuals, up to 240, who have recently been diagnosed with COVID-19 via the national testing programme in order for the trial team (at the Royal Free London NHS Foundation Trust known in these notes as the "Royal Free") to tell them about the FLARE clinical trial and invite them to enrol. The FLARE trial (phase II study) is investigating two antiviral drugs for early COVID-19 disease, with the aim of interrupting viral replication, thereby shortening the duration of symptoms and reducing risk of complications. Initially the applicant is requesting twice weekly drops of data over a two week period, with the option for additional drops of data in proceeding weeks. The following observations were made on the basis of the draft application and supporting documentation only. **IGARD Observations:** Noting that the Health Research Authority guidance was clear that any sponsors of a trial should be considered a Data Controller, that the applicant set out clearly why the University College London (UCL), as sponsor, was not considered a joint Data Controller. Or, citing the NHS Digital DARS Standard for Data Controllers / Data Processors, should UCL be considered a joint Data Controller, as borne out by the facts, to update the application accordingly. IGARD members suggested that section 5 of the application be updated to confirm that the funder will not have influence on the design or outcomes nor suppress any of the findings of

	the research and that a copy of the most recent funding letter be uploaded to NHS Digital's customer relationship management system (CRM) for future reference. In addition, and noting that the Royal Free had a number of bases in London, to confirm if any other bodies, based on a factual analysis, should be included as Data Controllers or Data Processors. IGARD members noted that the applicant had requested initially four drops of approximately 100 citizen's data over a two week period in order to recruit to the trial approximately 240 people, however IGARD suggested that the applicant may wish to consider requesting **more** citizen data per drop of data to ensure sufficient uptake. Noting that the legal basis cited for disseminating the data is COVID-19: Regulation 3 (4) of the Health Service (Control of Patient Information) Regulations 2002 (COPI), IGARD members suggested that confirmation (for example by way of an email between colleagues) explaining why and how this research and use fits under COPI be uploaded to CRM. With reference to the ethics review and subsequent substantial amendment made to the clinical trial Protocol (which, amongst other things, extended the remit beyond key workers), IGARD members queried if a more recent ethical approval had been sought. In addition, and noting the change in recruitment methods and specific use of NHS Digital data, had the ethics committee been fully appraised of the changes? NHS Digital should also ensure that all relevant and latest versions of all materials used by the FLARE trial team, including but not limited to, any revised Patient Information Sheet (PIS) be uploaded to CRM. IGARD members noted that the version of the PIS provided referred to this being a study of Key Workers and provided a templated letter to be completed by unnamed "study site". IGARD members noted in section 5(a) of the application that "*The trial team will decide whether to apply the Telephone Preference Service (TPS) under their own discretion.*", noting that in their view, in these circumstances, that TPS should be respected and applied to those citizens and before contact is made by the Trial Team. In addition, IGARD members suggested that the Trial Team be given a script, for example, which clearly outlined TPS and National Data Opt-outs (NDO) and explained how a citizen may elect to subscribe to either or both of those services, and the differences between the two. IGARD members noted in section 5(a) of the application reference to "*General geographical location within London…*" and suggested this was updated to correctly reference that the postcode was being used. IGARD members noted in section 3(c) reference to "*The common law duty of confidentiality is addressed by…*" and suggested this first sentence about "reasonable expectations" was removed, since it was not relevant. Separate to this application, IGARD members suggested that NHS Digital look to whether there could be the functionality to create data-set or research specific opt-outs, in addition to citizens being able to apply for the NDO. NHS Digital noted that they would be looking to update the application and bring it back to next week's COVID-19 response meeting, IGARD members were supportive of this approach. **Significant risk areas:** Data Controllership, updated Ethical Support.

2.3	NIC-420168-K4N1F University of Bristol **Background:** This was an update following a briefing and education session update from the University of Bristol at the COVID-19 response meeting on the 8th December 2020 and the presentation of a draft application for a longitudinal linkage collaboration (consent) focusing on the Avon Longitudinal Study of Parents & Children (ASLPAC) (NIC-13133-B7B3K) and Southall & Brent Revisited (SABRE) (NIC-148100-6RFK9 / NIC-148407-LRP3M / NIC-86954-Y0R2N) consented cohorts at the 15th December 2020. NHS Digital noted that due to unforeseen circumstances a number of comments made previously had not been updated in the application or supporting documentation. NHS Digital also noted that ASLPAC had been removed from the application. The following observations were made on the basis of the draft application and draft supporting documentation only. **IGARD Observations:** IGARD members noted the update from NHS Digital and that a tracked change application had been provided covering some of the previous points raised, and offered their support to DARS and the applicant. IGARD members reiterated their previous comment from the 15th December 2020 in relation to the application: to expressly address the number of years requested for Hospital Episode Statistics Admitted Patient Care (HES APC) and provide a justification for the c. 30 years of data request, citing NHS Digital's DARS Standard for Data Minimisation. IGARD members reiterated their previous comment from the 15th December 2020 that: due to the volume and richness of the data, it was unclear to IGARD members how it could be classed as "anonymous" in terms of the of the General Data Protection Regulation (GDPR). If the applicant was certain that the data was anonymous in terms of GDPR, at all stages of the processing, then a clear and careful analysis, referencing the appropriate resources, should be provided (and suggested this may be in the applicant's DPIA). In addition, and reiterating their comment from the 15th December 2020 meeting that: when the application is presented to a future business as usual (BAU) meeting in January, NHS Digital should undertake a full review of the consent materials and that this detailed analysis be provided as a supporting document with regard to what the consent covers and if there are any inconsistencies between the scope of the consent and the proposed processing. Noting that this application was to be presented to a future Profession Advisory Group (PAG) in relation to the GP Data for Pandemic Planning & Research (GDPPR) data and before its presentation at a future business as usual (BAU) meeting, IGARD members suggested that clarification be sought with regard to what the GP data was being used for and to ensure it aligned, to ensure the appropriate data minimisation (as per NHS Digital's DARS Standard for Data Minimisation), or to provide a justification of the use of relevant GP cluster codes. IGARD members noted within the published section 5 a number of references to appendices and suggested that these references be removed, if not accessible to the public. IGARD members queried reference to "*NHS authorities*" within the application and suggested that this phrase was updated or quantified.

	IGARD members noted reference in section 5 of the application to "*high volume of contracts*" and suggested that this wording was updated to be clear that this was in reference to the anticipated large number of agreements for sub-licencing. In addition, reference was made to the University of Bristol storing data in section 2(b) of the application and IGARD members queried why they would be storing data if they were using a Trusted Research Environment (TRE). IGARD members noted reference to staff being based at the University of Edinburgh, however since they were not listed as a Data Controller or Data Processor, that an explanation of their role should be given in section 5 of the application, for transparency. In addition, and noting that IGARD members did not usually comment on grammatical errors as such, suggested that the reference to "*studies institution*" was changed to "*study institution(s)*" to reflect that each individual study will have a DSA (and each study may have more than one home institution). IGARD members noted that the data retention section did not align with the agreement length (as is usual practice with DSAs) and suggested this was reviewed. Noting the regulatory and legal frameworks impacting on the retention of data, if the applicant had a proposed data retention time frame in mind, IGARD suggested that this is also reflected in the transparency materials provided/to be provided to cohort members as they are advanced in tandem with the application. IGARD members noted section 10 of the application referenced that "*applications for profit making will not be accepted…*", but suggested that this wording be updated so as not to unduly restrict the use of the data in the TRE. **Significant risk area:** analysis of level of data sitting in TRE (with reference to GDPR analysis/anonymous data).
2.4	<u>NIC-382794-T3L3M University of Oxford</u> **Background:** This was an amendment application (v2) to add in Covid-19 UK Non-hospital Antigen Testing Results (pillar 2) data, COVID-19 Hospitalisations in England Surveillance System (CHESS) Data, Second Generation Surveillance System (SGSS) data, receive more Civil Registration (Deaths) data, receive one more drop of Secondary Uses Service (SUS) data, and add additional data processors as they were co-applicants on the NIHR New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) grant. QResearch is a database of linked medical records that has been used, and continues to be used, by a variety of research projects undertaken by UK universities, from reviewing the safety of antidepressant medicines to studying factors to predict variations in survival rates for cancer patients. The database is widely used for medical research into the causes of disease, its natural history, treatment and outcomes. QResearch commenced in 2003 in order to improve access for research to primary care data and will continue for the foreseeable future. The data requested are linked to the existing QResearch database so it can be used for medical research. The QResearch database consists of the coded pseudonymised electronic health records from primary care patients registered with approximately 1,500 general practices spread throughout the UK. In addition to coded data from the GP electronic record, the QResearch database also includes cancer registration data supplied directly by Public Health England, following approval by Trent MREC and Secretary of State for Health.

	IGARD Observations: IGARD members were supportive of the application and importance that the data under this application should continue to flow to the applicant in order to inform the appropriate construction and revalidation of the algorithm. IGARD members noted that this was their first sight of the application and relevant supporting documentation, and that this would be reflected in the observations and comments made. IGARD members noted that overarching amendment application, *NIC-240279 University of Oxford: D27 QResearch-Oxford Data Linkage Project*, and supporting documentation had been previously considered at the COVID-19 response meeting on the 21st April 2020 and that this application had proceeded via NHS Digital's DARS SIRO Precedent. IGARD members had noted that the application and by inference any "spin off" application were not suitable for NHS Digital's precedent route and that they wished to review this application again when it comes up for renewal, amendment or extension. However, the abstract noted a number of incorrect phrases that should be updated namely, removing reference to "*Since approval by IGARD in April 2020...*" since the COVID-19 response meeting is not quorate and cannot provide recommendations (as per the published Standard Operating Procedure for the COVID-19 response meeting) and removing reference to "*IGARD has NOT identified the application as one that it wishes to see when next being considered for approval. DAO has noted that the not for precedent noted in the IGARD minutes below related to the main agreement not this application.*", since IGARD had specifically requested to see both the overarching and by inference any future applications. Noting NHS Digital's DARS Standard for Data Controllers / Data Processors and noting the inclusion of additional Data Processors, suggested that a review be undertaken as supported by the facts that the four additional Data Processing organisations were described accurately, (for example ICNARC on a previous application had been considered a joint Data Controller). IGARD members suggested that section 1 be updated to reflect the up to date time line, in that the University of Nottingham's roles and responsibilities **had been** transferred to the University of Oxford. IGARD suggested that reference to the "*ICO's "Anonymisation: managing data protection risk" code of practice*" be removed from sections 1 and 5, since it is no longer current. IGARD members suggested that section 1 be updated to correctly reference "***pseudonymised** at source*" rather than "*anonymised at source*". Noting the Dancing House Consulting (Data Processor) SLSP was last reviewed in May 2016, IGARD members suggested that this be reviewed by NHS Digital or to consider alternate arrangements, such as a honorary contract. IGARD members queried if other backup storage locations should be listed in section 2(b). IGARD members noted that section 2(c) listed the territory of use as "*worldwide*", however the special condition in section 6 noted the territory of use as "*EEA*" (due to staff being based in Spain and Italy) and suggested that the territory of use was aligned throughout the application **and** in line with any geographical restrictions which may be present for certain of the datasets requested.

	Noting that the application also stated that access to the data would be undertaken at the University of Oxford campus, but then referenced remote working within the application, IGARD members suggested confirmation be sought that the security requirements for remote access had been deemed satisfactory by NHS Digital's Security Team and a special condition be inserted in section 6 that set out any remote working security considerations. IGARD members noted that section 3(a) was incomplete and suggested that for any data being used via other data sharing agreements (DSAs) for the purposes in this application, that they be listed in, or as a note to, section 3(a). Noting the NHS Digital DARS Standard for Data Minimisation and the significant volume of data being requested, that a justification be set out of the value and necessity to receive all the requested data (and confirmation that **all** the data requested will be used solely for the Covid-19 specific processing outlined in this application). NHS Digital flagged the non-compliant GDPR privacy notice in April 2020, and since no update was available, and given the high-profile nature of this processing, IGARD suggested that the privacy notice be reviewed to ensure that it was GDPR compliant including, but not limited to, an explanation as to how this data is being used for the COVID-19 risk stratification including machine learning and production of algorithms. In addition, that a special condition be inserted in section 6 that the applicant will publish a GDPR compliant privacy notice within 1 month of the receipt of the data under this application. IGARD noted in section 5(a) of the application reference to "*Strategic decisions about the GP data are taken by a Management Board representing the interests of EMIS and the University of Oxford…*" and suggested that this was replaced with an explanation of the QResearch Advisory Board which advises the Management Board. IGARD members noted that sections 5(c) and 5(d) should be updated to more accurately reflect recently realised outputs and benefits including, but not limited to, the COVID-19 risk stratification algorithm for by GPs, set out the benefits of the algorithm generally and more specifically how this algorithm is used in the COVID-19 pandemic work, as per NHS Digital's DARS Standards for sections 5(c) and 5(d). IGARD noted that this application, once updated, should be presented at next Tuesday's COVID-19 response meeting. IGARD members advised 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). **Significant risk areas:** Accurate recording of Data Controller / Data Processor responsibilities. Public transparency of processing.
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.