Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 22 October 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Data Access Request Service (DARS)
Dave Cronin	Data Access Request Service (DARS) (Observer: Item 2.6)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS)
Denise Pine	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Tracy Taylor	Data Access Request Service (DARS)
Gemma Walker	Data Access Request Service (DARS) (Observer: Item 2.6)
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 that as part of her role at King's College London, she used the ONS Longitudinal Study data (NIC-194340-D6F3B), but noted no specific connection with the

	application or staff involved. It was agreed this did not preclude Nicola from taking part in the discussions about this application, however agreed that she would not participate in making a recommendation about the application. Maurice Smith noted a professional link to Liverpool University Hospital NHS Foundation Trust (NIC-161422-Q0K1M Royal Liverpool University Hospital) but noted no specific connection with the application or staff involved. It was agreed this did not preclude Maurice from taking part in the discussions about this application, however agreed that he would not participate in making a recommendation about the application. **Review of previous minutes and actions:** The minutes of the 15th October 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	IQVIA Ltd: PROVENT - A Phase III Randomized, Double-blind, Placebo-controlled, Multi-center Study in Adults to Determine the Safety and Efficacy of AZD7442, a Combination Product of Two Monoclonal Antibodies (AZD8895 and AZD1061), for Pre-exposure Prophylaxis of COVID-19 (Presenter: Louise Dunn / James Gray) NIC-409290-L1F3L **Application:** This was a new application to utilise the COVID-19 Permission to Contact (CV19 PtC) dataset, for the purpose of recruiting participants in the PROVENT vaccine trial. The PROVENT trial is a Phase III, randomized, double-blind, placebo-controlled, multi-country, multi-center study assessing the safety and efficacy of a single dose of AZD7442 (× 2 intramuscular (IM) injections) compared to placebo for the prevention of COVID-19. NHS Digital has agreed to work in partnership with the National Institute of Health Research (NIHR) to build and host a first of type online Permission to Contact (PtC) Service on NHS.uk, where members of the public can register their details and give their permission to be contacted by researchers working on NIHR approved UK coronavirus vaccine trials about participating in those trials. The initial mailout will aim for 5,000 potential participants to be contacted. The aim is to recruit the first patient into the trial on the 2nd November 2020. NHS Digital advised IGARD that ethics approval was requested on the 15th October 2020, however the applicant was still awaiting an outcome on this. **Discussion:** IGARD queried whether AZD7442 was a vaccine, noting that the application specifically referred to *"vaccine"*, and the online sign up service for the COVID-19 Permission to Contact (CV19 PtC) dataset specifically referred to *"coronavirus vaccine studies"*. It was discussed that this was not necessarily a bar to the application, but it would have implications for the content of the patient invitation e-mails that would be issued. NHS Digital advised that they had discussed this with NIHR, who had confirmed that all studies approved and supported by NHS Digital's Vaccine Taskforce were able to use the registry of which this was one; and that any communication to the cohort would have ethical approval and would be appropriately worded. IGARD noted the update from NHS Digital in relation to the outstanding ethics approval request, and asked that once the applicant received the response, the evidence was provided that ethics approval was in place. IGARD also asked that a copy of the e-mail communication text provided to the Ethics Committee was provided, to confirm that it clearly outlined the

	difference between monoclonal antibody pre-exposure prophylaxis and a vaccination. IGARD asked that both the ethics approval and e-mail communication were uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD noted that *"IQVIA Ltd"* and *"IQVIA LTD Technology Services"* were referenced within the application, and asked that the application was updated throughout to ensure the correct IQVIA entity was used. Noting the update from NHS Digital, IGARD queried the number of participants that the trial was aiming to recruit, noting that this was not clear within the application, and asked that the application was updated throughout to reference this information. IGARD noted the list of inclusion criteria in section 5(b) (Processing Activities) and queried the reference to *"Military personnel residing or working in high-density settings including but not limited to barracks, ships, or close quarters working environments"*; and advised that if military personnel were recruited, the applicant should ensure that they have made the appropriate enquiries for this, which included, but were not limited to, the Ministry of Defence and the Ministry of Defence Research Ethics Committee (MODREC) to ascertain if further approvals were required, and asked thar section 5 (Purpose / Methods / Outputs) was updated to reflect this. IGARD noted that the applicant was wanting to start recruitment into the trial on the 2nd November 2020, and queried how realistic this was, noting that ethics approval had not been received as yet; and suggested that that the applicant may wish to revise the reference to the start date for the recruitment to the trial to ensure it is achievable, for example stating when they *"aim"* to start the recruitment. NHS Digital advised IGARD that the applicant had sent through some additional text to be included in section 5(e) (Is the Purpose of this Application in Anyway Commercial) to ensure any commercial aspects were transparent. IGARD noted the revised wording, and suggested that this was tweaked to be less conditional, and asked that section 5(e) was updated with revised wording, and in addition, and for transparency, that the public facing section 5(a) (Objective for Processing) also included the updated text. Separate to this application, IGARD and NHS Digital agreed that it would be useful to have a discussion on the PTC, for example how many participants had been identified as eligible, how many participants had been recruited into trials and how evidence was being built to support the work of the CV19 PtC dataset. **ACTION:** IGARD and NHS Digital to further discuss the CV19 PtC at a future IGARD meeting. **Outcome:** recommendation to approve subject to the following condition: 1. In respects of the ethics approval: a) To provide a copy of the evidence that the ethics approval is in place. b) To provide a copy of the e-mail communication text provided to the Ethics Committee and to confirm that this makes clear the difference between monoclonal antibody pre-exposure prophylaxis and vaccination. c) To upload a copy of the ethics approval and e-mail communication to NHS Digital's CRM system. The following amendments were requested: 1. To update the application throughout to ensure the correct IQVIA entity is used. 2. To update the application throughout to reference the number of participants that they are aiming to recruit.

	3. If recruiting military personnel, to ensure they have made the appropriate enquires, including (but not limited to) MODREC, to approve their involvement and update section 5 to reflect this. 4. To update the commercial purpose in section 5(e) and replicate in section 5(a). The following advice was given: 1. IGARD suggested that the applicant may wish to revise the reference to the start date for the recruitment to the trial to ensure it is achievable. It was agreed the condition would be approved out of committee (OOC) by the Deputy IGARD Chair.
2.2	<u>University of Oxford: RAPid Testing fOR Covid-19 (RAPTOR-C19) (Presenter: Louise Dunn) NIC-396119-C8W3W</u> **Application:** This was a new application to permit access to data already held or due to flow under NIC-381683-R6R6K (University of Oxford) and NIC-21083-B6C5J (University of Surrey) already stored in the RCGP Research Surveillance Centre (RCGP RSC), where participants had provided individual patient consent for use of their data as part of 'Rapid Community Point-Of-Care Testing for COVID-19' (RAPTOR-C19). The aim is to assess the diagnostic accuracy of multiple current and emerging point-of-care tests (POCTs) for active or past COVID-19 infection in the community setting. Public Health England (PHE) and the Royal College of General Practitioners (RCGP) are Joint Data Controllers; the RCGP RSC is based at the University of Surrey; and Public Health England (PHE) holds a contract with the Royal Collage of Practitioners (RCGP) who in turn hold a contract with the University of Surrey to deliver information to support surveillance and monitoring of vaccine efficacy on Influenza. **Discussion:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD also noted the importance of the study. IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 22nd September 2020, however noted that the minutes from this meeting had not been included in section 1 (Abstract), and asked that this was updated with a copy of the minutes as per usual process. IGARD noted that NIC-21083 covered identifiable flows of data under Regulation 3, Health Service Control of Patient Information (COPI) Regulations 2002 and has a special condition that it cannot be used for research purposes. IGARD queried whether how this was compatible with the proposed research use and whether the existing agreement would need revision. IGARD also noted that data supplied under NIC-381683 was pseudonymous and queried how data relating to RAPTOR-C19 participants would be identified. IGARD noted that the application stated the RCGP and PHE were joint Data Controllers, however queried the role of the University of Oxford, in particularly noting that supporting document 1.1, the adult Patient Information Sheet stated that the Data Controller was the University of Oxford; and in addition, supporting document 4, the study protocol, stated the study was being driven by the University of Oxford, and the academic and strategic leads were both University of Oxford employees. IGARD asked that the organisations involved with the study were assessed against NHS Digital's Data Access Request Service (DARS) Data Controllers Standard; and that the Data Controllers listed within the application accurately reflected the factual situation.

	IGARD queried if there was a parental consent form for children and young people, noting that this had not been provided as part of the papers for reviewing, and were advised by NHS Digital that there was a parental form, and that this should have been included as part of the meeting pack. IGARD noted the update from NHS Digital and asked that a copy of the parental consent form was provided, and that this was uploaded to NHS Digital's Customer Relationship Management (CRM) system. In addition, IGARD queried if NHS Digital had undertaken an analysis of the consent materials provided, and asked that a copy of this was provided. IGARD noted that section 3(c) (Patient Objections) stated that patient objections had not been applied because the data was not considered confidential. IGARD queried this, and asked that conformation was provided as to how the Common Law Duty of Confidentiality was being addressed, for example via consent. IGARD also advised that when Opt-outs and objections were referenced, it should be clear which were being referred to, noting that, for example, the surveillance centre may apply their own. IGARD noted the volume of data that the study was requesting access to, and queried if they required access to all of the datasets to address the purpose of the work outlined, and asked that this was assessed in line with NHS Digital's DARS Data Minimisation Standard, and whether further data minimisation could be undertaken. In addition, IGARD queried which of the datasets requested were being processed specifically for RAPTOR C-19 and asked that confirmation was provided. IGARD had a lengthy discussion with regard to some of the information included within the application, and noted that it was not relevant to the study, and asked that the application was revised throughout, to emphasise more clearly the RAPTOR C-19 study; and that any references to other studies, were only included where it impacted on the RAPTOR C-19 study; and that any irrelevant text was removed. IGARD also noted that the outputs listed in section 5(c) (Specific Outputs Expected) and the Benefits in section 5(d) (Benefits) were not all relevant to the RAPTOR C-19, and asked that both sections were updated to specifically focus on the outputs and benefits of the RAPTOR C-19 study only. IGARD noted that when the application was discussed at the IGARD – NHS Digital COVID-19 Response meeting on the 22nd September 2020, there was reference in some of the supporting documents to the 'Oxford Royal College of General Practitioners Clinical Informatics Hub' (ORCHID), and in addition, noted the reference to this within supporting document 4,the study protocol, however noted that this was not referred to within the application; and asked that section 5 (Purpose / Methods / Outputs) was updated to clarify the use of the ORCHID platform. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. In relation to data controllership: a) To assess the Data Controllers against NHS Digital's DARS Data Controllers Standard. b) To ensure that the Data Controllers listed reflect the factual situation. 2. In relation to the consent materials: a) To provide a copy of the parental consent form. b) To upload a copy to NHS Digital's CRM system.

	c) To provide a copy of NHS Digital's analysis of the consent materials. 3. To confirm how the applicant is addressing the Common Law Duty of Confidentiality. 4. In respect of data minimisation: a) To assess the data requested against NHS Digitals DARS Data Minimisation Standard. b) To confirm which datasets are being processed for RAPTOR C-19. 5. To revise the application throughout to emphasise more clearly the RAPTOR C-19 study, and that any reference to other studies, is only where it impacts on the RAPTOR C-19 study; and to remove any irrelevant text. 6. To update section 5(c) and section 5(d) to focus on the RAPTOR C-19 study only. 7. To update section 5 to clarify use of the ORCHID platform. 8. To clarify in section 3(c) the various opt-outs and objections. 9. To update section 1 to include a copy of the historical IGARD meeting notes.
2.3	University of Oxford: R15 - The Platform Randomised trial of INterventions against COVID-19 in older peoPLE (PRINCIPLE) trial (Presenter: Louise Dunn) NIC-373132-D3Y7P **Application:** This was a new application to permit access to data already held or due to flow under NIC-381683-R6R6K (University of Oxford) and NIC-21083-B6C5J (University of Surrey) already stored in the RCGP Research Surveillance Centre (RCGP RSC), where participants had provided individual patient consent for use of their data as part of the 'Platform Randomised trial of INterventions against COVID-19 In older people' (PRINCIPLE) trial. The aim is to be the national Primary Care platform trial for UK COVID-19, assessing the effectiveness of trial treatments in reducing the need for hospital admission or death for patients with suspected COVID-19 infection aged ≥50 years with serious comorbidity, and aged ≥65 with or without comorbidity, and during time of prevalent COVID-19 infections in the context of current care delivery. Public Health England (PHE) and the Royal College of General Practitioners (RCGP) are Joint Data Controllers; the RCGP RSC is based at the University of Surrey; and Public Health England (PHE) holds a contract with the Royal Collage of Practitioners (RCGP) who in turn hold a contract with the University of Surrey to deliver information to support surveillance and monitoring of vaccine efficacy on Influenza. **Discussion:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD also noted the importance of the study. IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 28th April and the 22nd September 2020, however noted that the minutes from this meeting had not been included in section 1 (Abstract), and asked that this was updated with a copy of the minutes as per usual process. IGARD noted that NIC-21083 covers identifiable flows of data under Regulation 3, Health Service (Control of Patient Information) Regulations 2002 and has a special condition that it cannot be used for research purposes. IGARD queried whether how this was compatible with the proposed research use and whether the existing agreement would need revision. IGARD also noted that data supplied under NIC-381683 was pseudonymous and queried how data relating to PRINCIPLE participants would be identified. IGARD noted that the application stated the RCGP and PHE were joint Data Controllers, however queried the role of the University of Oxford, in particularly noting that supporting document 2, the adult Patient Information Sheet stated that the Data Controller was the University of Oxford. IGARD asked that the organisations involved with the study were

	assessed against NHS Digital's Data Access Request Service (DARS) Data Controllers Standard; and that the Data Controllers listed within the application accurately reflected the factual situation. IGARD noted that section 3(c) (Patient Objections) stated that patient objections had not been applied because the data was not considered confidential. IGARD queried this, and asked that confirmation was provided as to how the Common Law Duty of Confidentiality was being addressed, for example via consent. IGARD also advised that when Opt-outs and objections were referenced, it should be clear which were being referred to, noting that, for example, the surveillance centre may apply their own. IGARD noted the volume of data that the study was requesting access to, and queried if they required access to all of the datasets to address the purpose of the work outlined, and asked that this was assessed in line with NHS Digital's DARS Data Minimisation Standard, and whether further data minimisation could be undertaken. In addition, IGARD queried which of the datasets requested were being processed specifically for PRINCIPLE and asked that confirmation was provided. IGARD had a lengthy discussion with regard to some of the information within the application, and noted that it was not relevant to the study, and asked that the application was revised throughout, to emphasise more clearly the PRINCIPLE study; and that any references to other studies, were only included where it impacted on the PRINCIPLE study; and that any irrelevant text was removed. IGARD also noted that the outputs listed in section 5(c) (Specific Outputs Expected) and the Benefits in section 5(d) (Benefits) were not all relevant to the PRINCIPLE study, and asked that both sections were updated to specifically focus on the outputs and benefits of the PRINCIPLE study only. IGARD noted within the study protocol that one of the trial statisticians was based in the USA, and asked that section 5 was updated to clarify if this statistician had access to any of the study data. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD advised that they had previously requested an update in relation to the RCGP privacy notice in the main route application and that this was still outstanding. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. In relation to data controllership: a) To assess the Data Controllers against NHS Digital's DARS Data Controllers Standard. b) To ensure that the Data Controllers listed reflect the factual situation. 2. In relation to the consent materials, to provide a copy of NHS Digital's analysis of the consent materials. 3. To confirm how the applicant is addressing the Common Law Duty of Confidentiality. 4. In respect of data minimisation: a) To assess the data requested against NHS Digitals DARS Data Minimisation Standard. b) To confirm which datasets are being processed for PRINCIPLE. 5. To revise the application throughout to emphasise more clearly the PRINCIPLE study, and that reference to other studies is only where it impacts on the PRINCIPLE study; and to remove any irrelevant text.

	6. To update section 5(c) and section 5(d) to focus on the PRINCIPLE study only. 7. To clarify in section 3(c) the various opt-outs and objections. 8. To update section 1 to include a copy of the historical IGARD meeting notes. 9. To update section 5 to clarify if the trial statistician based in the USA has access to the study data.
2.4	<u>NHS North and East London Commissioning Support Unit (CSU): DSfC - Pseudo Person-Household Analytics to assess wider social determinants of health (Presenter: Duncan Easton) NIC-183870-V0T3Y</u> **Application:** This was a new application for pseudonymised Improving Access to Psychological Therapies (IAPT) Data Set, Personal Demographic Service (PDS), SUS for Commissioners, Mental Health Services Data Set (MHSDS), Community Services Data Set (CSDS), Children and Young People Health Services (CYPHS) Data Set. The London Borough of Islington requires pseudonymised data for use in the Islington Advancing Applied Analytics project to improve public health in Islington, and the targeted commissioning of services relevant to the needs of the population in the borough. This project aims to achieve this by linking health records with local authority council records (including social care, education and housing), at a household level, using pseudonymised Unique Property Reference Number (UPRN) to create a pseudonymised dataset of linked health and social records for households in Islington. **Discussion:** IGARD noted that supporting document 6, the draft privacy notice, stated that individuals had the right to opt of Islington Borough Council Public Health Team receiving or holding their personal identifiable information; and queried if data relating to individuals who had opted out would be sent from NHS Digital and what would happen when there was no corresponding match. IGARD also queried if NHS North and East London CSU held the key to reverse the pseudonymisation, and asked that confirmation was provided. IGARD queried the statement in section 5(b) (Processing Activities) that *"NEL Commissioning Support Unit then allow access to the processed, pseudonymised and linked data to the London Borough of Islington.",* which was contradicted within the application, and asked that confirmation was provided whether the data flowing was going back from NHS North and East London CSU to the Local Authority as this was not clear within the application or the data flow diagram provided. IGARD noted in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) that the applicant was linking NHS Digital data with housing data, and advised that NHS Digital should satisfy themselves that there was an appropriate legal bases for the linkage; and asked that section 1 and section 5 were updated with confirmation of the legal bases for the council to link NHS Digital data with the housing data. IGARD noted that section 3(c) (Patient Objections) stated that patient objections had not been applied, and asked that clarification was provided as to various Opt-outs and objections that could be applied, for example Type 1 objections and local authority opt-outs. IGARD discussed the purpose of the application, specifically noting the statement in section 5(a) (Objective for Processing) that *"The project is a proof of concept pilot…",* and asked that the application was updated throughout to reflect that it was a pilot, and to remove reference to all future work. In addition, noting the pilot status, IGARD also asked that the outputs in section 5(c) (Specific Outputs Expected) and the benefits in section 5(d) (Benefits) were updated and expressed in conditional terms. In addition, IGARD queried the information within supporting document 3, the request to NHS England for Primary Care Registration data, that referred to the secondary purpose as being

	"research", and were advised by NHS Digital that in previous iteration of the application it may have been referred to as research and this may be an error. IGARD noted the update from NHS Digital, and asked that the application was updated throughout to clarify whether the data was being used for the purpose of research. IGARD noted in supporting document 3, the reference to the National Institute of Health Research (NIHR) and University College London (UCL), and asked that section 1 was updated to clarify the roles of these organisations within the project. IGARD queried the Article 9 General Data Protection Regulation (GDPR) legal basis stated within the application, and noted that this differed from the Article 9 legal basis within the Data Protection Impact Assessment (DPIA), and asked that the application and the DPIA were aligned to state the correct Article 9 legal basis. IGARD noted that section 1 stated that NHS Digital's Security Advisor was satisfied with the use of Cloud storage, and asked that the abstract was amended to remove the statement, and to insert into section 1(b) (Data Processor(s)) as per the agreed process. IGARD noted the volume of data that the study was requesting, and queried if they required access to all of the datasets to address the purpose of the work outlined. IGARD asked that this was assessed in line with NHS Digital's DARS Data Minimisation Standard, and whether further data minimisation could be undertaken; and that section 3 (Datasets Held / Requested) and section 5 (Purpose / Methods / Outputs) were updated to justify the volume of data requested. IGARD queried if, in light of the involvement of research and PhD students, whether research ethics was required and, in addition, that the PhD students had the appropriate approvals from their educational institutions, and asked that confirmation was provided. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** Recommendation to defer, pending: 1. To provide confirmation as to whether NHS North and East London CSU holds the key to reverse the pseudonymisation. 2. To confirm in section 1 and section 5 the legal bases for the council to link NHS Digital data with the housing data. 3. In respect of the Proof of Concept Pilot: a) To update the application throughout to reflect the pilot and remove reference to all future work. b) To ensure the outputs and benefits are expressed in conditional terms. 4. To update the application throughout to clarify whether the data is being used for the purpose of research. 5. To update section 1 to clarify the role of UCL and NIHR as referred to in the supporting documents. 6. To ensure the Article 9 GDPR legal basis is aligned in the application and DPIA. 7. To insert the reference to the cloud storage security assurances, in section 1(b). 8. To update section 3 and section 5 to justify and align the volume of data requested with NHS Digital's DARS Data Minimisation Standard. 9. To clarify in section 3(c) the various opt-outs and objections. 10. To provide confirmation if in light of the involvement of research and PhD students, whether research ethics is required and that the PhD students have the appropriate approvals from their educational institutions. 11. To provide confirmation if the data flowing is back from the CSU to the LA.

2.5	NHS West Lancashire CCG: DSfC - NHS West Lancashire CCG IV, RS, Comm (Presenter: Duncan Easton) NIC-41605-Q7C3C **Application:** This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Children and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data, National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs). It was also an amendment application to 1) add Microsoft as a Data Processor for Cloud storage, 2) to add Amazon Web Service as Data Processor for Cloud service, 3) to add NHS Fylde and Wyre CCG as a Data Processor for the purpose of population health management, 4) to remove West Lancashire CCG as the Data Processor as they are the named Data Controller, 5) to remove Blackpool Teaching Hospitals NHS Foundation Trust as they no longer supply IT infrastructure, 6) to add e-Referrals data for commissioning purposes, 7) to add Mental Health Services Data Set (MHSDS) to the application for the purposes of Risk Stratification. The overall purpose is for Invoice Validation (IV) which is part of a process, by which providers of care or services are paid for the work they do, Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. The application was been previously considered on the 18th June 2020, when IGARD had deferred pending: to update the application throughout to accurately reflect the role of Liaison Financial Service Ltd; to provide confirmation if Liaison Financial Service Ltd are receiving the flow of e-Referrals data; and if so why and how this fit in with the processing activities; In respect of the privacy notice: a)To clarify how the remedial action plan previously set out by DAAG has been actioned; b) To update to provide further details on the profiling and any other automated decision making in relation to the Risk Stratification processing activities; to review the Article 9 legal basis provided for the e-Referral Service for Commissioning data; and either amend if appropriate, or provide an explanation as to why the legal basis stated is correct; to provide further clarification in section 5(a) of the professional roles of the *"users"* referenced; to revise section 5(a) to ensure that any marketing type wording is only used once; to amend the references in section 5(b) and section 5(c) to state that the NHS patient number is '**the'** identifier, instead of *"the only identifier"*; to review the document throughout to review any hyperbolic statements made, for example *"improving the quality of referrals"* in section 5(c); to complete the yielded benefits in section 5(d) (iii) with relevant examples; to update section 3(b) to reflect that the e-Referral Service for Commissioning data is identifiable; to amend the reference to controls in section 5(a) and 5(b) to address both role **and task** based access control; to update section 1 with the standard wording to confirm that in respect of the Cloud computing, NHS Digital Security Team have assessed and are satisfied; and 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. **Discussion:** IGARD noted that the application had been updated to reflect all of the comments previously made. IGARD asked that following the updates that had been made to the application since the last review in respect of the profiling and automated decision making in relation to the Risk

	Stratification processing activities, that section 5 (Purpose / Methods / Outputs) was updated to provide further information on this. IGARD noted that the application referenced two cloud storage platforms, Microsoft Limited and Amazon Web Services, and asked that the application was updated with a further explanation for the use of the two cloud storage data processors. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices; and asked that a special condition was inserted in section 6 (Special Conditions) that within 1 month of signing the Data Sharing Agreement (DSA), the applicant will have published a General Data Protection Regulation (GDPR) compliant privacy notice. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5 to provide further details on the profiling and automated decision making in relation to the Risk Stratification processing activities. 2. To update the application to include an explanation for the use of two cloud storage data processors. 3. To insert a special condition in section 6 that within 1 month of signing the DSA, the applicant will have published a GDPR compliant privacy notice.
2.6	<u>Royal Liverpool University Hospital: A Risk-adjusted and Anatomically Stratified Cohort Comparison Study of Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneurysms (UK-COMPASS). (Presenter: Denise Pine) NIC-161422-Q0K1M</u> **Application:** This was an amendment application to 1) request a re-supply of HES Admitted Patient Care (APC) and Diagnostic Imaging Data Set (DIDS) for extract one including additional operation codes, 2) to add Mortality data and DIDS data for extract two, 3) to add the University of Liverpool as a Data Controller, 4) to add an additional justification for the use of GDPR legal bases', 5) to update the purpose for requesting mortality data, 6) to justify the data minimisation 7) to add clarification of the role of the University of Liverpool as a joint Data Controller 8) to reflect the change of organisation name from Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBGHT) to Liverpool University Hospital NHS Foundation Trust 9. to clarify that all individuals who will be processing the data will be substantive employees of either the Liverpool University Hospital NHS Foundation Trust or the University of Liverpool, 10) to include newly generated outputs 11) to add further detail regarding the involvement of PhD and postgraduate students. Abdominal aortic aneurysm (AAA) is a common condition where the aorta, the largest artery, begins to bulge abnormally. Usually this expands over years and can eventually burst, causing fatal internal bleeding. When an emergency life-saving operation is possible, they have a high failure rate. A planned AAA repair operation prevents a burst aneurysm. The aim of the study is to answer the question identified by National Institute for Health Research - Health Technology Assessment (NIHR-HTA) Commissioning Board: What are the clinical and cost-effectiveness of strategies for the management of juxtarenal abdominal aortic aneurysm, including fenestrated endovascular repair. **Discussion:** IGARD noted and commended the efforts that had been undertaken on this application by NHS Digital and the applicant. IGARD noted the statement in section 3(c) (Patient Objections) *"Patients wishing to opt of sharing their data will be directed to a member of the study team who will ensure their data is not requested from NHS Digital"*, and asked that this was removed as it was incorrect.

	IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices; and asked that a special condition was inserted in section 6 (Special Conditions) that within 1 month of signing the Data Sharing Agreement (DSA), the applicant will have published a General Data Protection Regulation (GDPR) compliant privacy notice. **Outcome:** recommendation to approve The following amendments were requested: 1. To remove the text from section 3(c) that refers to being *"directed to a member of the study team"*. 2. To insert a special condition in section 6 that within 1 month of signing the DSA, the applicant will have published a GDPR compliant privacy notice.
2.7	<u>Office for National Statistics (ONS): ONS Longitudinal Study (Presenter: Garry Coleman / Tracy Taylor) NIC-194340-D6F3B</u> **Application:** This was a new application for identifiable Demographics data, for the purpose of a longitudinal study (LS). The study has linked records at each census since the 1971 Census, for people born on one of four selected dates in a calendar year. These four dates were used to update the sample at the 1981, 1991, 2001 and 2011 Censuses. Life events data are also linked for LS members including births to sample mothers, deaths and cancer registrations. The latest update to the LS added data from life events that happened in 2017. The LS now holds data relating to approximately 1.2 million people. NHS Digital advised IGARD that data disseminated for this purpose was previously undertaken via a Memorandum of Understanding (MoU) between the respective organisations rather than a Data Sharing Agreement (DSA). NHS Digital advised that they had received confirmation from NHS Digital's Information Governance (IG) that they were content that the correct legal bases was being used. **Discussion:** IGARD noted and supported the efforts of NHS Digital and ONS in moving the agreement from a MOU to a formal DSA. IGARD noted the update from NHS Digital in respect of NHS Digital's IG confirming that they were content that the correct legal bases had been cited in the application. IGARD asked that a copy of the advice was provided and that this was uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD also asked that section 1 (Abstract) was updated to reflect the IG advice received, and that any historical information that was no longer relevant was removed. IGARD noted that cohort sizes were not included within section 3(a) (Data Access Already Given) and section 3(b) (Additional Data Access Requested), and asked that this was updated to reflect the correct cohort numbers. In addition, IGARD also asked that further information was included in section 1 and section 5 (Purpose / Methods / Outputs), in respect of both the cohort numbers **and** further details of what each cohort related to. IGARD noted the reference in section 5(a) (Objective for Processing) to ONS' Research Accreditation Panel (RAP), and asked that further information of this Panel was provided, including clarification that RAP had reviewed the application and had approved the permissive route of the approval.

	IGARD also asked that section 5 was updated to provide further details of RAP in terms of the constitution and remit of the research accreditation of the Panel and if the Panel reviewed internal research use of the data, as well as those applying for sub-licence use of the data. IGARD queried the reference in section 5(b) (Processing Activities) *"NHS Digital will return files with LS numbers and success criteria."*, and asked that further clarity was provided on what was meant by success criteria as this was not clear. IGARD noted that section 5(d) (Benefits) iii (Yielded Benefits) contained links to some of the excellent benefits that have been achieved from the use of the longitudinal study, and asked that this be updated further to include a high-level summary of key examples accruing to the health and care system for transparency. IGARD noted that section 3(c) (Patient Objections) stated the statutory exemptions for the Opt-outs, however asked that this was updated to also include the statute exemptions. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices; and asked that a special condition was inserted in section 6 (Special Conditions) that within 1 month of signing the Data Sharing Agreement (DSA), the applicant will have published a General Data Protection Regulation (GDPR) compliant privacy notice. In addition, IGARD noted ONS' progress with regards to transparency but would encourage them to make further progress to ensure transparency of all materials used in the longitudinal study. **Outcome:** recommendation to approve 1. In respect of the IG advice: a) To provide a copy of the IG advice confirming the legal bases. b) To ensure that the IG advice is uploaded to NHS Digital's CRM system. c) To update section 1 with the IG advice and ensure all historical legal bases information is removed if not relevant. 2. In respect of the cohort numbers: a) To clarify in section 1 and section 5, the cohort numbers and what each cohort relates to. b) To update section 3(a) and section 3(b) with the correct cohort numbers. 3. In respect of the ONS Research Accreditation Panel: a) To clarify if the Panel have reviewed this application and approved the permissive route of approval. b) To update section 5 to provide further details in terms of the constitution and remit of the research accreditation of the Panel. c) To clarify in section 5 if the Panel reviews internal research use of the data as well as those applying for sub-licence use of the data. 4. To provide further clarity in section 5(b) to the reference to *"success criteria"*. 5. To update the yielded benefits in section 5(d) (iii) to include a high-level summary of key examples accruing to the health and care system. 6. To insert a special condition in section 6 that within 1 month of signing the DSA, the applicant will have published a GDPR compliant privacy notice. 7. To update section 3(c) to quote the statute as well as the statutory exemption. The following advice was given: 1. IGARD noted ONS' progress with regards to transparency but would encourage them to make further progress to ensure transparency of all materials.

3	Returning Applications Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
4	COVID-19 update To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 20th October 2020 can be found attached to these minutes as Appendix B.
5 **5.1**	AOB: NIC-381078-Y9C5K - Health Data Research UK IGARD noted that following the 15th October 2020 meeting, when IGARD recommended for approval subject to conditions. 1. In respect of the addition of NICE as a Data Controller, to provide or confirm that all of the appropriate documentation as required of a Data Controller TRE is in place, including (but not limited to); a) The joint Data Controller Agreement as per Article 26 of GDPR; b) The appropriate transparency notice published; c) Confirmation that NICE has acknowledged and is compliant with the relevant Special Conditions to the DSA. NHS Digital had taken the decision to disseminate the data. The IGARD Chair had been informed of this out of committee (see appendix A). There was no further business raised, the Deputy IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 16/10/20

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-381078-Y9C5K	Health Data Research UK	15/10/2020	1. In respect of the addition of NICE as a Data Controller, to provide or confirm that all of the appropriate documentation as required of a Data Controller TRE is in place, including (but not limited to); a) The joint Data Controller Agreement as per Article 26 of GDPR; b) The appropriate transparency notice published; c) Confirmation that NICE has acknowledged and is compliant with the relevant Special Conditions to the DSA.	IGARD members	NHS Digital's SIRO	NHS Digital's Associate Director, Data Access confirmed SIRO approval to the IGARD Chair and the IGARD Secretariat on the 19/10/2020
NIC-345789-L9Q7J	University of Surrey	03/09/2020	1. To clearly articulate in section 3 and section 5, the justification for the large volume of data requested both in terms of the number of fields and timescales. 2. In respect of the GMC consultant code: a) To provide clarification in section 3(b) that the GMC consultant code is not treated as an identifiable field.	IGARD members	IGARD Chair, under Chair's Authority	To insert a special condition: "*Upon renewal or amendment, the published sections of the agreement (section 5) which focus on the justification for the volume of data handled, should either be revised to ensure they are in a form suitable for a lay*

			b) To provide a clear justification in section 5(b) of the requirement of the GMC consultant code for linkage purposes. c) To confirm in section 5, if the GMC consultant code is removed or replaced with a study ID key once the linkage has taken place.			*reader or include a brief summary of the key points in language readily accessible by a lay reader*."
NIC-402963-P0Y5D - The University of Oxford	NIC-402963-P0Y5D - The University of Oxford	24/09/2020	1. NHS Digital to provide a suitable response to PAG whether the processing outlined can be achieved with NHS Digital's TRE. 2. The applicant to formulate a plan addressing how the outputs from the GP dataset can be shared with the RCGP and the BMA at the same time. 3. To provide written confirmation from IG that the flow of data does not breach the SPL direction or any other restrictions on use of shielded patient data.	IGARD members	OOC by IGARD members	N/A
NIC-08472-V9S6K	UK Biobank	24/09/2020	1. With reference to the PAG point 1: a) NHS Digital to collate a brief summary with the relevant sections of the consent materials that would support the processing of GDPPR data. b) To upload the summary on to NHS Digital's CRM system.	IGARD members	OOC by IGARD members	N/A
NIC-392201-S6C3W	Dr Foster Limited	01/10/2020	1. To provide a clear justification in section 5 for what purpose (if any) the customer Trusts may wish to re-identify patients; and to confirm that the use of any such data is compatible with treating the data as not being owed a Duty of Confidence.	IGARD members	OOC by IGARD members	N/A

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

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

- NIC-41524-N9J9N NHS Greater Preston CCG
- NIC-47139-R5G3C NHS Southport and Formby CCG
- NIC 90135-P7Z0F NHS Morecambe Bay CCG

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, 20th October 2020

In attendance (IGARD Members):	Paul Affleck (Specialist Ethics Member)
	Dr Imran Khan (Specialist GP Member)
	Dr Geoffrey Schrecker (Specialist GP Member / Deputy Specialist Chair)
In attendance (NHS Digital):	Vicky Byrne-Watts (DARS – item 2.3)
	Duncan Easton (DARS – item 2.2)
	Liz Gaffney (DARS)
	Karen Myers (IGARD Secretariat)
	Heather Pinches (DARS – item 2.1)
	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	<u>Permission to Contact (no NIC number available)</u> **Background:** This was a verbal update to discuss whether Permission to Contact (PtC) applications could now progress under a NHS Digital Precedent. PtC applications had been discussed a number of times at the COVID-19 response meetings on the 23rd June, 7th July, 4th August and the IGARD BAU Thursday meetings. Two applications have now been approved through IGARD Thursday meetings and a third is due for review this Thursday. The following observations were made on the basis of the verbal briefing only **IGARD Observation:** NHS Digital noted that a number of PtC applications were in the system to be presented to IGARD and if consideration should be given to a Precedent approach. IGARD noted that all applications need to align with the information presented to individuals when they joined the

	PtC service. Any applications where this may be ambiguous would **not** be suitable for a Precedent route. IGARD noted that any agreed Precedent would need to follow NHS Digital's agreed processes for Standards and Precedents and that the criteria for an application proceeding down a Precedent route be clearly defined. In addition IGARD noted that any consent and transparency materials should be reviewed to ensure any invitations regarding non-vaccine related trials are covered. Also, that the published parts of section 5 need to clearly articulate any commercial aspects of the application and that transparency materials are kept up to date.
2.2	<u>NIC-396095 Cheshire & Merseyside STP</u> **Background:** This was a verbal update to a presentation at the COVID-19 Response Meeting on the 29th September and 6th October, to support a set of COVID-19 related population health analytics, designed to inform both population level planning for COVID-19 recovery and to support the targeting of direct care to vulnerable populations across the Cheshire and Merseyside Sustainable Transformation Partnership (STP). NHS Digital noted that the application was being updated based on the previous discussions. NHS Digital noted that application would be proceeding via the SIRO Precedent due to the urgency of the application but had been brought to IGARD for any further advice. **IGARD Observations:** IGARD members noted the update from NHS Digital with regard to the number of joint Data Controllers and reiterated their previous comments with regard to addressing Article 26 of the General Data Protection Regulation (GDPR) to ensure a factual analysis of responsibilities had been undertaken and that their respective responsibilities are transparently available to the data subjects (using the NHS Digital DARS Standards for Data Controllers and Data Processors) and the rights of subjects in respect of that analysis. In addition, IGARD members reiterated their previous comments. They suggested that, noting the potential large volumes of data that may be requested that covered a large number of people and involved a number of data processors, that further clarification be sought on the number of processing locations and storage locations. In particular, clarifying whether all locations were being used to store all the data or whether locations were being used to store subsets of the data under different data controllership, tying back to the joint Data Controllership factual analysis. Noting NHS Digital's DARS Data Minimisation Standard and the request within section 3 of the application for data back to 2008, that a clear justification be provided for the time periods requested and how this linked to the current COVID-19 pandemic. It was not clear if the data was identifiable or pseudonymised. Linking back to the factual analysis of the joint Data Controllers, a clear explanation should be given of the data sensitivity, noting that the legal basis (the Health Service Control of Patients Information (COPI) Regulations 2002) allows for the processing of identifiable data. In addition, and noting that the applicant would be using the data disseminated within dashboards, to ensure that data was sufficiently timely in dissemination and to be clear within section 5 if the dashboards were historic or real time.

	One of the supporting documents referenced a Data Access and Data Asset Group containing public representatives. IGARD members suggested that the Board be described in full in the published portions of section 5 for transparency. Noting this application was for risk stratification in relation to vulnerability to serious harm from COVID-19 infection, that it be clear within section 5 that automated decision making would be taking place in respect of the direct care elements (including those patients not deemed vulnerable to adverse outcomes from COVID-19). IGARD members also noted that the text referring to National Data Opt-outs (NDOs) in section 3c should be updated, to accurately reflect that NDOs do not have to be applied in this context, but can be applied if judged appropriate.
2.3	<u>NIC-405749 Oxford recovery Trials (RECOVERY Trial)</u> **Background:** This was a verbal update to verbal and application presentations at the 28th April, 5th May, 12th May, 19th May, 7th July, 21st July and 22nd September COVID-19 response meetings. The RECOVERY trial, coordinated by Oxford University, is a national clinical trial aimed at identifying treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19. The RECOVERY trial team are looking to send a series of updates to participants to make them aware of the trial results to which they have contributed. The following observations were made on the basis of the verbal briefing only. **IGARD observations:** NHS Digital noted that it was initially thought that the University of Oxford would never directly receive the patient contact information because NHS Digital would be completing the communication on behalf of the University, however when NHS Digital spoke to the mail house provider they had contracted to send out the communications on their behalf, the 'return to sender' address will need to go on envelopes and for a small percentage of participants to whom the letter cannot be delivered, these would be returned to the University and therefore the University would receive contact information for those individuals. IGARD members discussed the legal gateway (consent) for the address details to be processed and reiterated their previous comments from the 22nd September that a brief note be included as a supporting document when the application is presented to a business as usual Thursday IGARD meeting, setting out how processing the address details and getting in contact with the cohort about all the various matters in the letter is compatible with the consent given by the cohort (the "no surprises" principle), noting that some members of the cohort may not have consented due to the severity of their illness. In addition, the legal basis should be clearly articulated for NHS Digital to provide the mail house provider with cohort contact details in order to mail out to the cohort. There was a discussion regarding the 'return to sender' details on envelopes and IGARD queried what the University of Oxford would do with returned mail. They also asked if the address could be NHS Digital's head office, since they were holding and processing the data on behalf of the University. In addition, IGARD members reiterated their comments from the 22nd September of the ability for the cohort to withdraw their consent from the study which was a key part of the justification

	for contacting the cohort and that all future iterations of the letter retain this text (including clear instructions on how to withdraw by phone, letter and email).
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.