Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 8 October 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Stuart Blake	Data Access Request Service (DARS)
Lizzie Cherry	Data Access Request Service (DARS) (Observer: item 2.6)
Dave Cronin	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Karen Myers	IGARD Secretariat
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 link with King's College London [NIC-174209-R8G8N] but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest.

	Nicola Fear noted that in her role at King's College London, she had a specific interest in the outputs of the Mental Health of Children & Young People Survey data that would be discussed under item 5.2. Paul Affleck noted professional links to the University of Leeds [NIC-332338-X1N2G] but noted no specific connections with the application and it was agreed that this was not a conflict of interest. Imran Khan noted a previous working relationship with some staff involved with the King's College London [NIC-174209-R8G8N] application. It was agreed this did not represent a substantive conflict of interest. **Review of previous minutes and actions:** The minutes of the 1st 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	<u>NHS Bristol, North Somerset and South Gloucestershire CCG**:** DSfC - NHS Bristol, North Somerset and South Gloucestershire CCG - IV, RS & Comm (Presenter: Duncan Easton) NIC-186885-Q1T3D</u> **Application:** This was an amendment application to 1) allow South Central and West Commissioning Support Unit to use Microsoft Azure, 2) add e-referral data as a commissioning product, 3) add ANS Group Limited as a Data Processor, 4) update South Central and West Commissioning Support Unit's processing and storage locations, 5) add the University of Bristol and the University of the West of England as Data Processors for the purpose of commissioning, and 6) add Amazon Web Services as a Data Processor. 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. **Discussion:** IGARD noted the addition of the two Universities as Data Processors, however noting that this was not for academic purposes, queried if it was for research; and asked that the CCG Population Health Management (PHM) Steering Group consider the processing and projects carried out by the Universities, and ensure that both the processing and the outputs produced related back to the permitted activities under this Data Sharing Agreement (DSA). IGARD also asked that section 5 (Purpose / Methods / Outputs) was updated to reflect that the Universities are carrying out commissioning work only; and in addition, that a special condition was inserted in section 6 (Special Conditions) that the Universities are **only** permitted to carry out activities that fit within the commissioning remit of the application. IGARD discussed and acknowledged that the pseudonymised data would **not** require Health Research Authority (HRA) Research Ethics Committee (REC) approval, but suggested the Data Controller and the CCG PHM Steering Group expressly considered whether or not the Universities had obtained all necessary internal approvals to carry out the activities, which may or may not include respective University REC approval.

	IGARD queried the funding arrangements in place for the Universities, and asked that confirmation was provided in section 5 of the source of any funding. In addition IGARD asked for clarification of if there were any commercial aspects of the funding, as this was not clear within the application. IGARD queried the description of Outcome Based Healthcare in section 1 (Abstract) as a *"private social purpose organisation"*, and asked that section 1 and section 5 were updated to correctly reflect that Outcome Based Healthcare is a Private Limited Company, that is linked to The King's Fund. IGARD noted the statement in section 1 and section 3(c) (Patient Objections) that patients were able to object to their data being processed for the purpose of risk stratification, and advised that this information was not stated within the published privacy notice. IGARD asked that the applicant ensured that the public facing transparency materials accurately described how members of the public can opt-out of Risk Stratification. In addition, IGARD also asked that the application was updated to accurately describe how members of the public can opt-out of Risk Stratification. IGARD noted that in section 1(a) and section 1(c) (Data Processor(s)) it 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 to avoid repetition. IGARD queried the information within the 'identifiability' column in section 3 (Datasets Held / Requested) and asked that this was updated to accurately record the flows of identifiable data flowing under this application. **Outcome:** recommendation to approve The following amendments were requested: 1. To ensure that the CCG PHM Steering Group considers the processing and projects carried out by the Universities, and to ensure that both the processing and the outputs produced relate back to the permitted activities. 2. To update section 5 to reflect that the Universities are carrying out commissioning work only. 3. To insert a special condition in section 6 that the Universities are **only** permitted to carry out activities that fit within the commissioning remit of the application. 4. In respect of the Universities' funding: a) To provide confirmation in section 5 of the source of the funding. b) To clarify if there are any commercial aspects of this funding. 5. To update section 1 and section 5 to reflect that Outcome Based Healthcare is a Private Limited Company, and is linked to The King's Fund. 6. In respect of Opt-outs: a) To ensure that the public facing transparency materials accurately describe how members of the public can opt-out of Risk Stratification. b) To update the application to accurately describe how members of the public can opt-out of Risk of Stratification. 7. To amend the abstract to remove the narrative on the cloud storage. 8. To update section 3 to accurately record the flows of identifiable data flowing under this application. The following advice was given: 1. IGARD acknowledged that the pseudonymised data would not require HRA REC approval, but suggested the Data Controller and the CCG PHM Steering Group

	expressly consider whether or not the Universities have obtained all necessary internal approval to carry out the activities, which may or may not include respective University REC approval.
2.2	University of Leeds: Presenter: Health related quality of life and clinical outcomes following acute myocardial infarction: linked EMMACE, HES and Civil Registration Mortality Data (Kimberley Watson) NIC-332338-X1N2G **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) Deaths and Admitted Patient Care, and Civil Registrations data, for the purpose of a study about health-related quality of life (HRQoL) in patients with myocardial infarction (MI) (heart attack). The overarching aim of this study is to enhance the EMMACE study consented cohort data using national healthcare data to investigate the association of changes in HRQoL and subsequent clinical outcomes (fatal or non-fatal) following MI including stroke, recurrent MI, heart failure, atrial fibrillation, deaths following MI. The number in the cohort for EMMACE 3 is 5,556 participants, recruited between 1st November 2011 and 17th September 2013; and the number in the cohort for EMMACE 4 is 9,343 participants, recruited between October 2013 and 24th June 2015, the total for both trials is 14,899 participants. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD queried which version of the consent material cohort members had been consented with, noting that there were two versions, version 1.1 and 1.2, and asked that confirmation was provided if any cohort members were consented with an earlier version of the consent materials than those provided as part of this review; and if so, to confirm that the proposed processing was compatible with any earlier consent materials. In addition, IGARD also asked that copies of the earlier consent materials were provided; and that a copy or copies of these documents were uploaded on to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted that the cohort numbers stated within the application and the supporting documents provided, for example the data flow diagram, were inconsistent, and asked that where appropriate these were reviewed and aligned to ensure the correct cohort numbers were stated. IGARD queried the references in the application to the applicant requiring NHS numbers, in light of the data being pseudonymised and the request for study IDs, and were advised by NHS Digital that this was an error. IGARD noted the update from NHS Digital and asked that the application was amended throughout to remove the references *"NHS numbers"* flowing. IGARD noted that supporting document 2.0, the study's General Data Protection Regulation (GDPR) transparency information paper, stated "If you withdraw from the study, we will keep the information about you that we have already obtained"; IGARD asked that section 5 (Purpose / Methods / Outputs) was updated with confirmation that **no** identifiers would be sent to NHS Digital for cohort members who had withdrawn from the study. IGARD noted that the references to the Data Security and Protection Toolkit (DSPT) compliant research environment were inconsistent in the application and asked that these were updated to ensure they were accurately described throughout.

	IGARD queried the reference within supporting document 3.0, the data flow diagram that analysis of the anonymised data would be conducted on the N:Drive, noting that the N:Drive was not covered by any of the Organisation Data Service (ODS) codes provided; and asked that the data flow diagram was updated to reflect that the N:drive would **not** be used for the purpose of analysis. IGARD queried the organisations listed in section 2(a) (Processing Location(s)) under 'organisation address' and noted that two separate institutes, Leeds Institute of Cardiovascular and Metabolic Medicine (LICAMM) **and** Leeds Institute for Data Analytics (LIDA) had been referred to, with one address, and asked that this was updated to verify the correct geographical location. IGARD noted the patient and public involvement (PPI) outlined in section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) and suggested, that in light of the funding arrangements by The British Heart Foundation, that this was updated further to expand on the PPI involvement and to reflect the activities outlined. In addition, IGARD also asked that the benefits in section 5(d) were aligned with NHS Digital's DARS Benefit Standard, including, but not limited to, how the research would benefit patients and the wider community. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the consent materials: a) To confirm if any cohort members were consented with an earlier version of the consent materials. b) If so, to confirm that the proposed processing is compatible with the earlier consent materials. c) To provide copies of the earlier consent materials if available. d) To upload a copy of the earlier consent materials to NHS Digitals CRM system. The following amendments were requested: 1. To ensure the DSPT compliant research environment is accurately described throughout the application. 2. To update the data flow diagram to reflect that the N drive will **not** be used for the purpose of analysis. 3. To review and align where appropriate the cohort numbers in the application and the supporting documents provided. 4. To update the processing locations in section 2(a) to verify the correct geographical location. 5. To amend the application throughout to remove the references to *"NHS numbers"* flowing. 6. To confirm in section 5 that no identifiers are sent for cohort members who have withdrawn from the study. 7. To update section 5(c) and section 5(d) to expand on the PPI involvement and to reflect the activities outlined, in light of the funding arrangements. 8. To align section 5(d) with NHS Digital's DARS Benefit Standard, including how the research will benefit patients and the wider community. It was agreed the conditions would be approved out of committee (OOC) by IGARD Members.
2.3	<u>King's College London: HES and NICOR data linkage for cardiac failure population analysis (Presenter: Kimberley Watson) NIC-174209-R8G8N</u>

	Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data, for the purpose of a medical research study, which aims to understand population-based, patient-level analysis of heart failure in England using a data set created by linking record level pseudonymised HES Admitted Patient Care (APC) and the National Institute for Cardiovascular Research Outcomes (NICOR) data between the years of 2013/4 and 2017/18. The study is aiming to quantify heart failure patients who suffer from repeat readmissions and evaluating the risk factors for repeat readmissions. The study will test the hypothesis that there are specific risk factors associated with repeat readmissions. It is King's College London hypothesis that a minority of patients account for the majority of re-hospitalisations, and therefore are at higher risk for worst clinical outcomes and the majority of the cost implications. By identifying risk factors, it will become apparent which, if any, are avoidable. It will then be possible to calculate the potential cost savings associated with preventing such avoidable admissions. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted the information provided both within the application and the funding letter from Heartfelt Technologies dated the 6th September 2018, and queried why they were not considered joint Data Controllers; for example, the statement that Heartfelt Technologies would *"provide input on analysis, and specify certain minimum criteria for analysis"*. IGARD asked that either a written explanation was provided based on the facts presented confirming why Heartfelt Technologies were **not** considered a joint Data Controller; or if they were considered a joint Data Controller, that the application was updated throughout to reflect this. IGARD also noted that Heartfelt Technologies were a commercial company and asked that for transparency, section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to reflect that Heartfelt Technologies was a commercial company. In addition, IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated there were no commercial aspects, and asked that this was updated to reflect the commercial aspects of the research outputs. IGARD noted that the legal bases for the processing was Legitimate Interests, and queried what the conclusion was for this, and asked that a written explanation was provided confirming why Legitimate Interests was considered the appropriate legal bases for King's College London to undertake the research. IGARD queried the information in section 3(b) (Additional Data Access Requested) that appeared to indicate the data would be released to the King's Technology Evaluation Centre (KiTEC) (part of King's College London), but not the bridging file that would be sent to NICOR. IGARD specifically queried the statement that this "*Does not include the flow of confidential data"*, and asked if the bridging file would contain NICOR's study specific ID for them to identify individuals and prepare an extract for KiTEC; and asked that section 1 and section 5 were updated to confirm, that KiTEC does **not** have the ability to re-identify any individuals within the dataset. IGARD also asked that section 3(b) was updated to include the bridging file that was flowing to NICOR, as although it was referred to, there was not a specific request for this. IGARD noted the information within the published privacy notice that individuals were able to withdraw from the pseudonymised dataset, and asked that this was revised to remove this statement as, given the data was pseudonymised and participants could not be identified, was incorrect. In addition, IGARD asked that the privacy notice was updated to reflect the National Data Opt-out guidance.

	IGARD noted the language used within section 5(a) and section 5(d) (Benefits) to patients *"suffering"* from heart failure, and suggested that these references were amended to refer to patients *"living"* with heart failure. IGARD noted that section 5(b) (Processing Activities) made specific reference to an academic paper, however the full title of the paper had not been completed, and asked that section 5(b) was updated with the full title of the academic paper. IGARD queried if there were any plans to involve wider patient and public involvement (PPI) and asked that further details be included in section 5(d). **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the data controllership: a) To provide a written explanation why Heartfelt Technologies are **not** considered joint Data Controllers. b) If Heartfelt Technologies is considered a joint Data Controller, to update the application throughout to reflect this. 2. To provide a written explanation as to why Legitimate Interests is considered the appropriate legal bases for KCL to undertake the research. The following amendments were requested: 1. To confirm in section 1 and section 5 that KiTEC does not have the ability to re-identify any individuals within the dataset. 2. To revise the privacy notice to remove any suggestion that individuals are able to withdraw from the pseudonymised dataset, and ensure this reflects the National Data Op-out guidance. 3. To update section 3(b) to include the bridging file that is flowing to NICOR. 4. In respect of the commercial aspect: a) To update section 1 and section 5 to reflect that Heartfelt Technologies is a commercial company. b) To update section 5(e) to reflect the commercial aspects of the research outputs. 5. To amend the references in section 5(a) and section 5(d) from *"suffering"* to *"living"* with the condition. 6. To complete the reference to the academic paper in section 5(b). 7. To update section 5(d) to include further details of the PPI. It was agreed the conditions would be approved out of committee (OOC) by IGARD Members.
2.4	<u>University College London: Understanding the health needs of mothers involved in family court cases (Presenter: Kimberley Watson) NIC-196263-J9Q7Z</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data, for the purpose of a study aiming to generate evidence about the health needs of mothers involved in public law care proceedings in England. University College London (UCL) are requesting to link an existing cohort of mothers and babies, held under a separate Data Sharing Agreement (DSA) (NIC-393510-D6H1D) with programme information from the Children and Family Court Advisory and Support Service (Cafcass). Women aged between 15 and 50 years, with at least one live birth recorded in the Hospital Episodes Database between 01/04/1997 and 31/03/2017 will make up the cohort, and it is estimated that there will be a maximum of 12 million women in this cohort. This cohort of women will be linked to Cafcass data on women involved in care proceedings between 01/04/2007 and 31/03/2019, which includes 113,191 mothers.

	There is clear evidence that mothers, whose children enter public care or are adopted, often have complex health needs, such as drug and/or alcohol misuse, exposure to violence, mental health problems as well as chronic physical conditions. The key study questions are, 1) are there health characteristics of vulnerable mothers that are associated with a high likelihood of care proceedings, 2) among mothers involved with care proceedings, what characteristics are associated with time to subsequent pregnancy, adversity related admissions and adverse outcomes related to court. NHS Digital advised IGARD that due to the volume of data requested, NHS Digital's Caldicott Guardian had been consulted on this application. **Discussion:** IGARD noted and supported the update from NHS Digital in respect of the involvement of the Caldicott Guardian with this application. IGARD noted the size of the proposed cohort's and queried what the justification was for the size of the control cohort, which was up to 12 million in relation to the size of the study cohort, which was 113,191;and asked that a clear written justification was provided for this, in light of the general consensus being that the size of the control cohort should be around five times that of the study cohort. In addition, IGARD also asked that when providing justification for the volume of data, this was aligned with NHS Digital's DARS Data Minimisation Standard and generally accepted research principles. IGARD noted that the Cafcass extract used for the study, would be minimised to only contain information on women aged 15-50 years who were party to section 31 applications, which is where local authorities have applied to have a child removed from parental supervision due to serious concerns for the child safety and wellbeing; and asked for further clarification in section 5 (Purpose / Methods / Outputs), if the study cohort included any woman for whom a section 31 order has been applied, **or** just those where the section 31 order has been upheld. IGARD noted the statement in section 1 (Abstract) that legal advice had been sought from NHS Digital's Information Governance, however advised this had not been provided, and asked that a copy was provided and that this was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted the statement in section 1 and section 5(a) (Objective for Processing) that "*Research must be approved by the Cafcass Research Advisory Committee*", and queried if all the supporting documents had been received from Cafcass, noting that IGARD had not received any confirmation that the Cafcass Research Advisory Committee had reviewed this application; and asked that confirmation was provided, and that an additional documents provided were uploaded to NHS Digital's CRM system. IGARD queried the policy questions outlined in light of the data that had been requested, for example reducing *"the unmet burden of health"*, and asked that confirmation was provided that these questions could be answered with the data disseminated under this application. In addition, IGARD noted that part of the study's objectives was to look at various aspects of the mental health of the mothers within the study cohort, and asked that section 1 was updated clarifying that this objective would be achievable without the Mental Health Minimum Data Set, as this had not been requested under this application. IGARD queried the information in the application that stated that the maximum number of postcodes matched to the Cafcass data was three postcodes, however noted that supporting document 3, the Data Flow Diagram, stated that this was five postcodes; asked that the application and Data Flow Diagram were aligned to reflect that the maximum number of postcodes linked was three.

	IGARD noted that supporting document 6, the study protocol, referred to the University of Lancaster and asked that clarification was provided in section 1 of their involvement in the study, noting that there was no reference to them within the application. IGARD noted the references within section 1 and section 5 to *"delivery"* and suggested that the word "*delivery*" was replaced with the term *"birth"*. IGARD noted the language used in the application when describing the cohort, for example "*vulnerable*" mothers / women, and suggested that this was reviewed. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested, and noted the specific point of advice made by Health Research Authority Confidentiality Advisory Group (HRA CAG), that the applicant may wish to consider engaging with a wide range of relevant groups, for example charities and third sector organisations, who could help reach, represent or advocate for the study cohort, and to ensure these efforts were reflected in section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits). **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the control cohort: a) To provide a clear written justification for the size of the control cohort in relation to the size of the study cohort. b) To justify and align the volume of data requested with NHS Digital's DARS Data Minimisation Standard and generally accepted research principles. 2. 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. The following amendments were requested: 1. To clarify in section 5 if the study cohort includes any woman for whom a section 31 order has been applied, or just those where the section 31 order has been upheld. 2. To provide conformation that **all** the supporting documents have been received from the CAFCASS Research Advisory Committee; and to upload a copy to NHS Digital's CRM system. 3. To provide confirmation that the policy questions posed can be answered with the data requested, for example, reducing the unmet burden of health. 4. To update section 1 to clarify that the objectives are achievable without receipt of the MHMDS. 5. To align the application and supporting document 3, to reflect that the maximum number of postcodes linked is three. 6. To clarify in section 1 the role of the University of Lancaster. 7. To replace the reference to *"delivery"* in section 1 and section 5 with *"birth"*. 8. To review the language in section 5 when describing the cohort, for example such as referring the mothers / women as *"vulnerable"*. The following advice was given: 1. IGARD suggested (and also noting the specific HRA CAG advice on this point) the applicant may wish to consider engaging with a wide range of relevant groups, for example charities and third sector organisations, who can help reach, represent or advocate for the study cohort, and to ensure these efforts are reflected in section 5(c) and section 5(d).

	It was agreed the conditions would be approved out of committee (OOC) by IGARD Members.
2.5	<u>University of Cambridge: Survival Improvement with Colecalciferol in Patients on Dialysis – The SIMPLIFIED Registry Trial (Presenter: Dave Cronin) NIC-24422-R3W3S</u> **Application:** This was a renewal application for identifiable Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data; and an amendment to 1) add Cambridge University Hospitals NHS Foundation Trust as a joint Data Controller, 2) to replace the HES Accident and Emergency (A&E) data set with the Emergency Care Data Set (ECDS), 3) the migration of MRIS products to the new Content Management System (CMS) data extracts, 4) the update of cohort consent materials, and 5) to ensure the deletion of specific fields in held data (MRIS reports). The SIMPLIFIED randomised controlled trial, which began in February 2017, aims to assess the effect of colecalciferol (vitamin D) supplementation versus standard care on health outcomes in patients with kidney failure receiving dialysis and will involve approximately 4,200 patients over a 7-8 year period. NHS Digital noted that the applicant's Data Sharing Agreement (DSA) had expired on the 26th July 2019. NHS Digital advised IGARD that there was incorrect information within section 5 (Purpose / Methods / Outputs) in respect of the process if members of the cohort wished to withdraw consent, and confirmed that section 5 would be updated to accurately reflect that if members of the cohort withdraw consent, then the applicant would not flow this data to NHS Digital, and that they would be withdrawn from the flagged cohort; and in addition, also confirmed that this would be inserted as a special condition in section 6 (Special Conditions). **Discussion:** IGARD noted the update from NHS Digital that the applicant's DSA had expired. IGARD also noted and supported the amendment to section 5, to accurately reflect that if members of the cohort withdrew consent, then the applicant would not flow this data to NHS Digital, and that they would be withdrawn from the flagged cohort; and the additional special condition that would be inserted in section 6 to reflect this. In addition, IGARD also queried how many withdrawals would be actioned, and asked that section 5(b) (Processing Activities) was updated with a clear explanation. IGARD noted that the cohort numbers within the application differed, and it was unclear as to how many individuals had already been recruited and how many still needed to be recruited, and asked that section 5 was amended to reflect the most recent cohort figures; and that section 5 was also updated with the aspirational cohort target. IGARD also asked that section 3 (Datasets Held / Requested) was reviewed and updated to accurately reflect the current and correct cohort size. IGARD discussed the applicant's consent materials and agreed with NHS Digital's assessment that they were broadly compatible with the processing outlined. IGARD noted that when the application was last reviewed on the 16th February 2017, they had suggested that the applicant may wish to revise their consent materials, and made a number of suggestions on specific areas to focus on. It was IGARD's view that the points made previously had **not** been addressed, and therefore, asked that a special condition was inserted in section 6 that upon renewal, the applicant would outline what steps had been taken to review the consent materials and points previously raised by IGARD.

	IGARD suggested that with regard to the arguable ambiguity in the consent materials, that the applicant either a) discussed the statement with the relevant Ethics committee, b) consulted with representatives of the cohort to ascertain what they take the wording to mean, or c) removed the statement that *"No information about you will be shared with any third parties not directly involved with this research"*. IGARD noted a number of acronyms in section 5 (Purpose / Methods / Outputs) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader such as *"EQ5D"*. IGARD noted comments from the applicant with regard to patient facing materials and advised that the Health Research Authority (HRA) template was an example to start from, not legally prescribed wording, and that any patient facing materials should reflect what was happening in the particular study. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome:** recommendation to approve The following amendments were requested: 1. To insert a special condition in section 6, that upon renewal, the applicant will outline what steps have been taken to review the consent materials and points previously raised by IGARD. 2. To update section 5 **and** to insert a special condition in section 6, that if members of the cohort withdraws consent, that the applicant will not flow this data to NHS Digital, and they will be withdrawn from the flagged cohort. 3. To update section 5(b) with a clear explanation as to how any withdrawals will be actioned. 4. In respect of the cohort numbers: a) To amend section 5 to reflect the most recent cohort figures. b) To include in section 5 the aspirational cohort target. c) To update section 3 to reflect the current correct cohort size. 5. To amend section 5 to ensure that all acronyms upon first use be defined and further explained, such as '*EQ5D*'. The following advice was given: 1. IGARD advised that the HRA template is an example to start from, not legally prescribed wording, and that any patient facing materials should reflect what is happening in the particular study. 2. With regard to the arguable ambiguity in the consent materials, IGARD suggested that the applicant either a) discuss the statement with the relevant Ethics committee, b) consult with representatives of the cohort to ascertain what they take the wording to mean , or c) remove the statement that "No information about you will be shared with any third parties not directly involved with this research". 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment.

	4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.6	<u>The National Institute of Cardiovascular Outcomes and Research (NICOR) Briefing Paper (Presenter: Stuart Blake)</u> The briefing paper was to inform IGARD that NHS Digital have been directed by the Secretary of State under section 254 of the Act to establish and operate a system for the collection and analysis of the information specified for this service for COVID-19 purposes. For all 7 NICOR datasets NHS Digital will be receiving a subset of English patients only (defined as patients treated in hospitals located in England). The seven datasets are, Adult Cardiac Surgery, Cardiac Rhythm Management, Congenital Heart Disease, Heart Failure, Myocardial Ischaemia National Audit Project (MINAP), Percutaneous Coronary Interventions (PCI), and Transcatheter aortic valve implantation (TAVI). Data will be used for COVID 19 purposes only, where external customers can access data via NHS Digital's Data Access Request Service (DARS) process. IGARD welcomed the briefing paper and looked forward to receiving an updated paper at a future IGARD meeting, and before any first of type applications are submitted. IGARD made the following additional comments: 1. To update the briefing paper to reflect whether NHS England is a joint data controller with HQIP. 2. To review the public-facing transparency information about the research that has taken place to date. 3. To confirm if any necessary IG approvals have taken place, including aligning with the Data Provision Notice.
3	<u>Returning Applications</u> 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>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 6th October 2020 can be found attached to these minutes as Appendix B.
5 **5.1**	<u>AOB:</u> <u>Commercial Purpose Standard (Presenter: Dave Cronin)</u> IGARD and NHS Digital reviewed NHS Digital's DARS Commercial Purpose Standard, and suggested some further updates / amendments. IGARD thanked NHS Digital for sharing this and the work that had been undertaken with updating the Standard and looked forward to seeing an updated version in due course.

5.2	Mental Health of Children & Young People Survey (Presenter: Stuart Blake) The Mental Health of Children and Young People survey provides data on the prevalence of mental health disorders in children and young people, aged 2-19 years old and living in England. The surveys have so far been conducted in 1999, 2004, 2007 (follow up of 2004 cohort) and 2017. NHS Digital provided IGARD with an update on the Survey, and advised that there had been delays due to the COVID-19 pandemic, however it was expected that the Direction may be signed in November 2020. 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 02/10/20

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-372269-N8D7Z	University College London	30/07/2020	1. To confirm the applicant has successfully secured ethics amendment approval, which addresses, inter alia: a) social media recruitment; b) children's assent materials limited to respiratory infections only or (if relevant) revised materials covering a wider range of reference points; c) the reference to *"5-years"* in the children's assent materials*;* d) the oversampling of the Polish community; and e) that REC have seen and approved version 7 of the protocol. 2. In respect of Data Minimisation: a) To address the data minimisation points raised in the IGARD – NHS Digital COVID-19 Response meeting on the 26th May 2020. b) To update the table in 3(b) accordingly.	IGARD members	IGARD Chair, under Chair's Authority	*Advice which should be considered and actioned upon update of the materials:* *The assent materials should explicitly state that a hospital visit related to a respiratory infection* ***could be any hospital visit within a certain number of days following a report of a respiratory symptom, or following serological evidence of respiratory infection and therefore, the researcher will require all hospital contacts for children.*** *To check the wording aligns with the adult consent materials in respect of the 5-years follow-up data.*

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

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

- None

Appendix B

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 6th October 2020

In attendance (IGARD Members):	Prof Nicola Fear (Specialist Academic Member)
	Kirsty Irvine (IGARD Lay Chair)
In attendance (NHS Digital):	Vicky Byrne-Watts (DARS)
	Dave Cronin (DARS)
	Cath Day (DARS)
	Liz Gaffney (DARS – Item 2 and 3.1)
	Dickie Langley (Information Governance)
	Karen Myers (IGARD Secretariat)
In attendance (external):	Emily Cross (IBM – item 2 only)
	Jerome Greutmann (IBM – item 2 only)
	Stephen Pettitt (IBM – item 2 only)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2	<u>IBM update</u> IGARD members were given a brief update to the IBM work underway in NHS Digital including improvements to the customer experience and current projects. It was agreed that this would be a weekly update to the COVID-19 response meeting. IGARD members thanked IBM and NHS Digital for the update.
3.1	<u>NIC-402417-N9Z5W UCL Partners</u> **Background:** this was a verbal update from NHS Digital with regard to the NHS Digital Cancer Trusted Research Environment (TRE) and an application from UCL Partners to access the Cancer TRE.

	The following observations are made on the basis of the verbal briefing only **IGARD Observations:** IGARD members welcomed the verbal update from NHS Digital with regard to the NHS Digital Cancer TRE and were supportive of the TRE approach. IGARD also noted that when previously discussed at the COVID-19 response meeting on the 8th September that a briefing paper or verbal update be provided for IGARD members with regard to the Cancer TRE by the relevant programme lead within NHS Digital in due course and before the first application is presented to the IGARD business as usual meeting (BAU). IGARD members noted the work undertaken to set up the Cardiovascular TRE and that NHS Digital ensure this was aligned and consistent with the approach taken there. IGARD suggested that consideration be given to the interplay between the Cancer TRE and Cancer Alliances who were already accessing cancer data, and that if there was a distinction between the two types of systems that this be clearly articulated within the application. IGARD members also noted a number of Data Controllers were involved and that NHS Digital undertake a factual analysis, as per NHS Digital's DARS Standard on Data Controllers and Data Processors. In addition, IGARD noted that should any Data Controllers be based outside of England and Wales that consideration be given of any legislation relating for instance to Northern Ireland, since the Health Service Control of Patients Information (COPI) Regulations 2002does not apply to Northern Ireland, and that appropriate special conditions may be needed . Exploration should be undertaken of any datasets that have been collected by NHS Digital under the COVID-19 Public Health Directions 2020 and which would sit within the TRE, since they would have to be destroyed once the direction expired (currently end of March 2021). In addition, if confidential patient information was being supplied to the TRE, consideration should be given, as to how the duty of confidentiality would be satisfied. IGARD members also suggested that consideration be given around data minimisation, noting NHS Digital's DARS Standard for Data Minimisation. IGARD members also noted that should any ethics approval be required, that it should be a broad approval to cover the programme of work, and not too narrow as to exclude the addition of projects as the TRE develops.
3.2	<u>NIC-374190-D0N1M Genomics England</u> **Background:** this was an update to the discussions at the COVID-19 response meetings on the 21st July, 16th June, 9th June and 19th May. NHS Digital had provided a number of supporting documents for consideration by IGARD following discussion with the applicant. NHS Digital noted that they had not provided an updated application summary for consideration. The following observations are made on the basis of the documentation provided. **IGARD Observations:** IGARD members noted that the specialist ethics member had joined a call with the applicant and NHS Digital and suggested that they provide a review of the documentation out of

	committee. In addition, NHS Digital should cross reference the notes from that telephone call with the updated documentation. NHS Digital noted that the ethical favourable opinion letter from NHS Lothian made reference to "…*the committee would also like to recommend that an application be made to CAG* and would appreciate seeing a copy of the CAG opinion letter when available*….". IGARD members suggested that NHS Digital discuss with the applicant the proposed timeframe for reconsenting or augmenting the current consent for the cohort and whether there is or is not need for part of the cohort to rely on s251 support. *Health Research Authority Confidentiality Advisory Committee (HRA CAG) IGARD members noted within the "Patient Information Sheet Aug" provided, reference to withdrawing from the study: "…*you are free to withdraw from this study at any time without giving reason and without detriment to your medical care. All samples that we hold for you would be destroyed…if you decide to withdraw from the study, no new information about you will be collected, but information that has already been collected will continue to be used for the study…*" and noted that since the two sentences seemed to contradict each other, that the documentation to be updated to clarify the potentially ambiguous withdrawal text. IGARD members noted that within the Patient Information Sheet reference to occupation: "…*We know that being older, male, having another health condition, being obese, being from a ethnic minority, occupation and low income all play a part in how sick people become*…" and suggested that in any future iteration of the Patient Information Sheet that a clearer explanation be given as to what was meant by the term "occupation", for example a certain occupation may have a higher risk profile than another occupation due to the number of people a person is in contact with. **Subsequent to the meeting** The IGARD specialist ethics member reviewed the submitted documentation out of committee and noted that the materials were compatible with NHS Digital flowing confidential patient information and in addition noted the applicant had clearly put a great deal of effort into their communications and the accessible animated messages. Should the Patient Information Sheet be updated in the future, IGARD advised the applicant consider a number of additional amendments including, but not limited to: updating current text to read "…*direct identifiers, such as you name and date of birth, are removed*…"; amending withdrawal wording to read "…*If I take part can I later withdraw*…"; and removing any contradictory text with regard to identifiability and withdrawal.
3.3	<u>NIC-15625-T8K6L CPRD / MHRA</u> **Background:** This was a brief update to updates received at the 26th May, 19th May and 12th May 2020 COVID-19 Response meeting. **IGARD Observations:** Due to presenter illness, IGARD members noted the brief update from NHS Digital that the updated application would be coming to a future IGARD business as usual (BAU) meeting for a full review.
3.4	<u>NIC-14709-Z2H2R i5 Health</u>

	Background: this was a verbal update from NHS Digital with regard to i5 Health amending their application to include GPES Data for Pandemic Planning & Research (GDPPR). The application had been previously considered by IGARD business as usual (BAU) meeting on Thursday, 27th August 2020. The following observations are made on the basis of the verbal briefing only **IGARD Observations:** IGARD members noted the proposed inclusion of the GDPPR data into a previously approved data sharing agreement (DSA) and that i5 Health had approached NHS X. IGARD members noted the GDPPR dataset was collected under the COVID-19 Public Health Directions 2020 and suggested that NHS Digital discuss with the Information Governance (IG) directorate the inclusion of this data on the amendment application to ensure the appropriate legal gateway was satisfied for this commercial applicant.
3.5	<u>NIC-396095-H1P1D NHS Arden & GEM / Cheshire & Merseyside STP</u> **Background:** This was a verbal update to a presentation at the COVID-19 Response Meeting on the 29th September, 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 discussion but was returning today to update IGARD members on the volume of proposed Data Controllers **IGARD Observations:** NHS Digital noted that they had discussed with the applicant the volume of proposed Data Controllers and that a factual analysis of the responsibilities had been undertaken, reducing the overall number to approximately 14 Data Controllers. IGARD members noted the update and suggested that further factual analysis be undertaken, using the NHS Digital DARS Standards for Data Controllers and Data Processors to ensure relevant parties to the Data Sharing Agreement (DSA) were clearly articulated within the DSA. Thought should also be given to any individuals or parties who may not be considered a Data Controller or Data Processor but may undertake work on behalf of them or involved in an advisory capacity; in such case the appropriate use of honorary contracts may be helpful.
4.	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.