Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 25th June 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
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:**
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Data Access Request Service (DARS) (Items: 2.4 to 2.8)
Catherine Day	Data Access Request Service (DARS) (Observer: 2.6 to 2.8)
Dr. Arjun Dhillon	Caldicott Guardian (item 2.4)
Louise Dunn	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS) (items 2.4 to 2.8)
Frances Hancox	Data Access Request Service (DARS)
Dickie Langley	Information Governance (IG) (Observer: 2.5 to 2.8)
Karen Myers	IGARD Secretariat
Richard Hatton	Clinical Informatics (Observer: 2.1 to 2.8)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:**

	The minutes of the 18th June 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>Dr. Foster Limited: Dr Foster Standard Extract Service Feed (Presenter: Frances Hancox) NIC-68697-R6F1T</u> **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration Data; and an amendment to add the Emergency Care Data Set (ECDS) including historic ECDS back to 2017 which is required to support the transition between the HES Accident and Emergency (A&E) and ECDS. The purpose is to help health and social care organisations to make better and faster decisions with data and insight and, ultimately, to benefit patients. This is delivered in three main strands, 1) Dr Foster tools and services, to provide management information, analysis and clinical benchmarking through online products and services, 2) bespoke analytics, to deliver customised projects to meet individual customer needs, 3) research for publication, to provide thought leadership in the field of healthcare data analytics, with the aim of improving the planning, delivery and outcome of health and social care. NHS Digital noted that subsequent to the submission of the application, an amendment had been made to the application allowing for NHS England to receive unsuppressed outputs from Dr Foster for the Getting It Right First Time (GIRFT) programme. **Discussion:** IGARD noted the amendment to the application and queried if NHS England had provided a Data Protection Impact Assessment (DPIA). IGARD thought it was appropriate in this instance to analyse, identify and minimise data protection risks where the processing of certain types of data may result in a high risk to the rights and freedoms of individuals (in this case unsuppressed outputs). IGARD asked that a special condition be inserted into section 6 (Special Conditions) stating that Dr. Foster could not flow NHS Digital data to NHS England / NHS Improvement until they were in receipt of a DPIA which expressly addressed the receipt of the GIRFT outputs with small number unsuppressed. In addition, IGARD asked that a copy of the DPIA be uploaded to NHS Digital's Customer Relationship Management (CRM) internal system as a further supporting document. IGARD requested further clarity in Section 5 (Purpose / Methods / Outputs) that NHS England / NHS Improvement (the recipients of the Dr. Foster outputs) would not re-identify the individuals, however the ultimate recipient i.e. the Trust could re-identify the individual for the purpose of direct care. IGARD also noted reference to '*all users working on the programme*' and asked for further clarity of this reference and how this will be regulated, for example by way of role and task-based access controls. IGARD noted that the overlap of the ECDS and HES A&E data, however, it was not clear in section 5 why the applicant required the two year overlap of data and suggested that either a justification was provided as to why they needed the (largely) duplicated two years of data, or to request a shorter timeframe to carry out requisite checks, with the option to request further data for comparison purposes if necessary. IGARD queried the privacy notice and information within supporting documentation provided as part of the review, and asked that further clarification was sought as to what was meant by the phrase '*further pseudonymisation*' and make clear what the '*further re-identification*' may

	be. In addition, it should be expressly stated that the national data opt-out would only apply to **some** of the data flowing under this Data Sharing Agreement (DSA), not all of the data. IGARD suggested that section 5(c) (specific outputs expected, including target dates) be updated to insert relevant indicative data for the outputs where possible, and given the volume of data requested. IGARD noted reference in section 1 (Abstract) and section 2 (Locations) to Dr. Foster's 'Dorset Rise' address, however since it had been indicated in section 1 that the processing location was moving from Dorset Rise to Mill Harbour during a previous iteration of the application summary, to check if Dorset Rise was still operational and if not to remove reference to it from the application. A number of acronyms were noted in section 5 and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use were expanded, clearly defined and that that a supportive explanation in a language suitable for a lay reader, for example (and not limited to) to expand the '*GIRFT*' acronym and provide an explanation in order to set the scene, and to expand the '*EPIKEY*' acronym. In addition IGARD noted that some of the information in section 5 was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader including reference to '*burden of care*' and that further sensitive consideration was given to the patient audience and how this type of language could be perceived. IGARD suggested that applicant may wish to consider effective patient and public involvement (PPI) since it was not clear within the application or supporting documentation if any PPI had been undertaken, which would appear appropriate given the scale of the data requested. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To insert a special condition in section 6, stating that Dr. Foster Limited may not flow NHS Digital data to NHS England / NHS Improvement unless they are in receipt of a DPIA that expressly addresses receipt of GIRFT outputs with small numbers unsuppressed. 2. In respect of the 2 years overlap of the ECDS and HES A&E data, to either provide a detailed justification of having 2 full years of (largely) duplicated data, or to produce a shorter timeframe to carry out the requisite checks, with the option to request further data for comparison purposes if necessary. The following amendments were requested: 1. NHS Digital to upload a copy of the DPIA on to their CRM system. 2. In respect of the proposed GIRFT wording: a) To clarify further that the recipients of the Dr Foster outputs (NHS England / NHS Improvement) may not re-identify the individuals, however the ultimate recipient i.e. the Trust can re-identify for the purpose of direct care. b) To expand the GIRFT acronym on first use and to provide an explanation of what this is, in order to set the scene. c) To provide further clarity on the reference to *"all users working on the programme"*, with an explanation of how this will be regulated, for example role and task-based access controls. 3. To Clarify in section 5 and the privacy notice: a) That the National Data Opt-out will only apply to **some** of the data flowing under this DSA. b) To clarify what the further pseudonymisation may be. c) To make clear what the further re-identification may be.

	4. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience (for example when referring to *"burden"*). 5. To check that Dr Foster Dorset Rise storage location is still operational, and if not, to remove from the application. 6. Given the volume of data requested, to insert indicative target dates for the outputs where possible. 7. To amend section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader. The following advice was given: 1. IGARD suggested that the applicant may wish to consider PPI involvement. It was agreed the conditions would be approved OOC by IGARD Members.
2.2	<u>Imperial College London: Imperial College London/Dr Foster Limited Standard Extract Service Feed (HES Amendment, Renewal/Extension) (Presenter: Frances Hancox) NIC-12828-M0K2D</u> **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration Data; and an amendment to add the Emergency Care Data Set (ECDS). The purpose is to identify measures of quality and safety in healthcare. ICL DFU's research themes are around developing and validating indicators of quality and safety of healthcare, particularly by GP practices, consultants, and NHS Trusts. This research finds variations in healthcare performance by unit, patient risk subgroups and risk prediction, risk adjustment and outlier detection for such indicators and variations, and any other methodological aspects as they arise. **Discussion:** IGARD noted that the overlap of the ECDS and HES A&E data however it was not clear in section 5 (Purpose / Methods / Outputs) why the applicant required the two year overlap of data and suggested that either a justification was provided as to why they needed the (largely) duplicated two years of data, or to produce a shorter timeframe to carry out requisite checks, with the option to request further data for comparison purposes if necessary. IGARD noted reference in section 1 (Abstract) and section 2 (Locations) to Dr. Foster's 'Dorset Rise' address, however since it had been indicated in section 1 that the processing location was moving from Dorset Rise to Mill Harbour during a previous iteration of the application summary, to check if Dorset Rise was still operational and if not to remove reference to it from the application. IGARD noted that a number of differing legal bases were listed under section 3 (Data Sets Held / Requested) and against each of the individual datasets and that they should be reviewed and where necessary updated to reflect the correct legal basis for each dataset held and requested. Section 5(b) (Processing Activities) referenced "*the data flow diagram is included with this Agreement…*" and suggested reference to the diagram be removed, since it would not be published on NHS Digital's Data Release Register. IGARD noted that the website link referenced within section 5(c) (Specific Outputs Expected, including Target Date) detailing the latest and historical publications should be reviewed and updated, since the last publication date was 2017. A number of acronyms were noted in section 5 and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use were expanded, clearly defined and that that a supportive explanation in a language suitable for a lay reader.

	IGARD suggested that applicant may wish to consider effective patient and public involvement (PPI) since it was not clear within the application or supporting documentation if any PPI had been undertaken since 2016 (based on supporting document 9 provided for review) and that the applicant may wish to re-engage with relevant PPI groups since this was a complex and wide-ranging study. **Outcome Summary:** recommendation to approve subject to the following condition: 1. In respect of the 2 years overlap of the ECDS and HES A&E data, to either provide a detailed justification of having 2 full years of (largely) duplicated data, or to produce a shorter timeframe to carry out the requisite checks, with the option to request further data for comparison purposes if necessary. The following amendments were requested: 1. 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. 2. To update section 5(b) to remove the reference to the data flow diagram. 3. To check that Dr Foster Dorset Rise storage location is still operational, and if not, to remove from the application. 4. To update section 3(a) to review and if necessary, to correct the legal reference for each dataset. 5. To review the website link setting out outputs in section 5(c) to ensure this reflects the most current information (presently 2017). The following advice was given: 1. IGARD suggested that since there has not been any public and patient involvement since 2016 (based on supporting document 9), that the applicant may wish to re-engage with relevant groups. It was agreed the conditions would be approved OOC by IGARD Members.
2.3	<u>Public Health England (PHE): NHS Health Checks: linking primary care dataset to hospital and mortality data (Presenter: Louise Dunn) NIC-201243-R7L2M</u> **Application:** This was an extension application for pseudonymised NHS Health Checks data for a further three years; and an amendment for linkage of the primary care data set 'NHS Health Checks' with hospital data and mortality data to estimate the impact of NHS Health Check attendance on health outcomes. The NHS Health Check is a national prevention programme which involves three components - assessment, awareness and management of the top seven risk factors driving the burden of non-communicable disease. In 2018, PHE and NHS Digital worked together to produce an Analytical Strategy for the data extraction, described as follows: process, health data, outcomes and models. Stage 1 and 2 - process and health data - have been the primary focus of the initial data analysis. PHE is now exploring stages 3 and 4 as an extension of its monitoring of the impact of the programme. Stages 3 and 4 will evaluate longer term outcomes following an NHS Health Check and explore the development of models to evaluate risk prediction, economic impact and interventions related to the check. **Discussion:** IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and that a review be undertaken by the applicant to ensure that reference to outdated legislation and opt-out terminology, such as the 'Data Protection Act 2018' and 'type 1 objections' are updated as appropriate.

	IGARD queried the inconsistences within the application when referring to the identifiers held by NHS Digital and asked that this was revised to ensure that where appropriate the term '*gender*' was replaced with the term '*sex*', if '*sex*' was the data set held by NHS Digital. IGARD requested that a duplicate paragraph of text in section 5(a) (Objective for Processing) starting "*As PHE has a very limited national monitoring system…*" be removed and that section 5 (Purpose / Methods / Outputs) be reviewed to remove any other duplicated information. IGARD noted in section 5(b) (Processing Activities) that the '*named analysts working on this project…only be viewing the data which will physically remain within on the server…*', however IGARD noted this appeared to be an incorrect statement since data would in fact be transmitted to an individual's laptop. The statement should be clarified to be clear that the data is not physically transferred from the server or to remove this statement if in fact it does not accurately reflect what is happening. IGARD noted reference to the '*8 risk factor*s' and a website link, however suggested that section 5(b) be updated to replace the link with the list of the eight risk factors, since this would then be published on NHS Digital's Data Release Register and in the public domain. IGARD noted that section 5(d) (Benefits) should be updated to expand on the benefits accruing directly to the patients and in addition how the outputs may be disseminated directly to the participants, since it was not clear how the benefits of attending a health check would be disseminated to inform patients. IGARD noted reference to the Data Security and Protection Toolkit (DSPT) which had been published for 2019/20 as baseline in November 2019 and suggested that section 6 (Special Conditions) be reviewed to ensure that the special condition inserted accurately reflected current developments. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve. The following amendments were requested: 1. To update section 6, to ensure the DSPT special condition reflects recent developments. 2. To update section 5(a) to remove any duplication of information. 3. To clarify the statement in section 5(b) that the data is not physically transferred from the server or to remove if this does not accurately reflect what is happening. 4. To update section 5(b) to replace the link provided with a list of the *"8 risk factors"*. 5. To update section 5(d) to expand on the benefits accruing directly to patients, and how the outputs may be disseminated directly to the participants. 6. To review the Privacy Notice to remove reference to outdated legislation and opt-out terminology. 7. To ensure that where appropriate the term *"gender"* is replaced with the term *"sex"*. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment 2. IGARD suggested that this application would not be suitable for NHS Digital's precedent route

2.4	University of Birmingham: The BASIL-2 trial: comparing the clinical and cost-effectiveness of revascularisation strategies for severe limb ischaemia (Presenter: Kimberley Watson) NIC-291863-S9M0X **Application:** This was a new application for identifiable Hospital Episodes Statistics (HES) Admitted Patient Care (APC) and Civil Registrations data for the purpose of a trial that builds on the previous Bypass vs Angioplasty in Severe Ischaemia of the Leg (BASIL) trial to determine whether a 'vein bypass (VB) first' or a 'best endovascular treatment (BET) first' revascularisation strategy represents the most clinically and cost effective treatment for severe limb ischaemia (SLI) due to below the knee (infra-geniculate) arterial disease. The four trial centres are based in Denmark and Sweden, the rest of the 50 trial hospital sites are located in the UK and the trial currently has a small cohort of 323 individuals recruited within England. The application was been previously considered on the 23rd January 2020 when IGARD had made a positive statement and were supportive of the application but were unable to make a formal recommendation as there was not a quorum of members able to comment on the application. NHS digital noted reference in section 5 (a) that *'no data provided under this agreement would be shared outside England and Wales, rather the Danish and Swedish trial sites may provide their outcome information to the UK trial sites for comparison purposes, but not for any record level linkage*' and that this sentence would be updated to be clearer. **Discussion:** IGARD noted that even though the consent materials provided as part of the review did not mention the fact that data would still flow after a participant had died, IGARD did not think that the consent materials were incompatible with the processing outlined in the application. IGARD also noted that this was an interesting and valuable study. Due to the current COVID-19 pandemic, IGARD noted that consideration was given as to whether the current Data Sharing Agreement (DSA) which permitted only the use of accessing the data at the Birmingham University Campus computer was a practicable solution, particularly with potential home working. Should the DSA permit data access via home computers, that a special condition be inserted in section 6 (Special Conditions) that it is permissible and to also insert the relevant NHS Digital security advisor's standard wording. IGARD noted in section 5(c) (Specific Outputs Expected, including Target Date) that the applicant was planning to disseminate outputs to a number of stakeholders, however suggested that the applicant may also wish to work with patient-facing third sector organisations who worked directly with those patients affected by the ailments outlined within the application, to ensure they were fully involved and the outputs disseminated to the wider public. In addition, and noting the good work undertaken in respect of lay member involvement and regular newsletter sent out to the participants, that this should be captured within section 5, which would also be published on NHS Digital's Data Release Register and in the public domain. IGARD noted the DSA end date was 2023 and that potentially the applicant may receive another drop of data in that year, however it was clear within the application and supporting documents provided for review that the study was due to end in 2022, and asked that an explanation be provided as to the apparent disparity between the two dates. **Outcome Summary:** recommendation to approve. The following amendments were requested: 1. Due to the current COVID-19 pandemic: a) To consider whether permitting access only on Birmingham University Campus computers is a practical solution, particularly with potential home working.

	b) If applicable, to update section 6, to insert a special condition that access via home computers is permissible as per NHS Digital Security Advisors standard wording. 2. To clarify why the study end date is prior to the last date of NHS Digital data received and explain the apparent disparity between the two dates. 3. To update section 5 to reflect the good work undertaken in respect of the Lay Member(s) involvement and the regular newsletters sent to participants. The following advice was given: 1. IGARD suggested that the applicant may wish to consider working with patient-facing third sector organisations who work with patients affected by the ailments outlined within the application, and to involve and ensure the outputs are disseminated to the wider public.
2.5	<u>The Health Foundation: Use of secondary care in England by international immigrants (Presenter: Kimberley Watson) NIC-114819-K5Z6Q</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) Outpatient, HES Critical Care, HES Accident and Emergency, HES Admitted Patient Care, Medical Research Information Service (MRIS) and Civil Registration (death) data. The Health Foundation are requesting that NHS Digital create a cohort of migrants for patients who are aged 18 years and over to HES A&E / OP / APC then to mortality data to compare the utilisation of secondary care in England by international migrants in comparison to the 'non-migrant' population, as well as estimating the cost of utilisation for migrants for each year of registration, from 2004 onwards. The application was previously considered on the 23rd January 2020 when IGARD had deferred but were unable to make a formal recommendation as there was not a quorum of members able to comment on the application. The deferral points were: to provide a positive statement of support from the NHS Digital Caldicott Guardian; to clearly define the purpose of the proposed research, including clarification in section 5(c) of how the outputs derived from the data requested would benefit the health and social care system; to remove reference(s) to *"medical research"* in section 1 where this is not relevant; to update section 5(a) with a clear rationale behind the work outlined (including, but not limited to, reference to *"charging back"* or recovering costs of healthcare for migrants); to provide further details of the referenced similar research that has previously been undertaken and outline the purpose of this research and how this research links to the previous research undertaken; to clearly address the moral and ethical issues relating to this study and previous research undertaken; to provide further clarity on the point at which the patient group 'UseMyData' will be involved with the study; to provide further clarity on the patient / public involvement in the project and how this has been utilised in the study design; to remove reference to any government / political policy benefit from the application; to amend section 5(a) to move the section outlining the *"two main priorities for the NHS"* to the beginning of this section; to provide further clarity on the reference in section 5(a) to *"ethnicity"*; to provide further details in section 5(a) of how the cohorts were created, specifically the rational on 'group 2', why they have 2 sub-groups within this and if they are going to be analysed separately; to provide further definition on the reference in section 5(a) to *"characterise patients";* to provide further information on the role of the University of Cambridge within the study, since the substantive employee involved in the study is an employee of the University; IGARD suggested that the applicant may wish to consider expanding the stakeholder group(s) involved and that these should be reflective of the patients that are the focus of the study; IGARD suggested the applicant may wish to review the term *"migrant"* throughout the application; IGARD suggested that NHS Digital satisfy itself that the

	application is designed to elicit genuine benefits to health and social care and not advancing a policy agenda. **Discussion:** The NHS Digital Caldicott Guardian asked that IGARD re-review the application and IGARD agreed to do so and invited the Caldicott Guardian to attend the meeting for this particular agenda item. IGARD noted that a number of NHS Digital's standards had not been met including, but not limited to, Standard 3 Data Minimisation, Standard 5(a) Objective for Processing and Standard 5(d) Expected Measurable Benefits. IGARD noted that the majority of the points they had raised previously on the 23rd January 2020 remained outstanding and noted the additional points: • No positive statement of support from the NHS Digital Caldicott Guardian had been received by IGARD. • The purpose and methodology of the proposed research was not clearly defined nor how the outputs derived from the data requested would benefit the health and social care system, as distinct from outputs that would inform social policy. • The objectives for processing were not clear within the application. • There was little engagement with individuals or the focus groups and no detail as to how participants were recruited. • The moral and ethical issues relating to this study and previous research undertaken were not fully addressed. • Noting the current sensitivities of immigration, these had not been addressed within the application. Additionally, disparate references to immigration, immigrant and migrants remained and reference to charging migrants for care. • There was no clear legal basis for the applicant to access the quantum of data requested. • Noting the aim to support commissioners, there was no explanation as to how this support would work or that there was a demand from commissioners for this data. • NHS Digital had undertaken a public interest test and were not supportive of the application. • IGARD noted NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** Noting the complexity of the application, the NHS Digital Caldicott Guardian asked IGARD to re-review the application, and IGARD agreed to do that. IGARD reached the conclusion that they were unable to recommend for approval and did not support the application*, and the Caldicott Guardian supported IGARD's recommendation. The Caldicott Guardian would not recommend that NHS Digital took any further action with regard to this application other than that recommended by IGARD. *IGARD noted that the following key NHS Digital Standards had not been met: Standard 3 Data Minimisation, Standard 5a Objective for Processing (including (but not limited to) Legal Basis, moral and ethical issues etc); Standard 5d Expected Measurable Benefits.
2.6	<u>Genomics England: R-26 GENOMICS ENGLAND: GenOMICC COVID-19 Study (Presenter: Louise Dunn / Garry Coleman) NIC-374190-D0N1M</u> **Application:** This was a new application for identifiable Mental Health Services Data Set (MHSDS), Community Services Data Set (CSDS), Civil Registration, Demographics, COVID-19 Hospitalization in England Surveillance System (CHESS), Hospital Episode Statistics (HES), Diagnostic Imaging Dataset (DID), Emergency Care Data Set (ECDS), COVID-19 Second Generation Surveillance System (SGSS), Secondary Uses Service Payment by Result

	(SUS PBR), Cancer Registration Data and GPES Data for Pandemic Planning and Research (GPDPPR). The purpose is for a national study aiming to provide detailed whole genome sequencing to 35,000 participants affected by COVID-19 and it is the aim to concurrently add high quality clinical data to aid the research effort; and would be available for analysis alongside the extant Genomics England data set of the 100,000 Genomes Project. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 28th April, 5th May, 12th May, 16th June and 23rd June 2020; and in addition, that this application had also been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (see Appendix B) on the 17th June 2020. By way of background, IGARD noted that when this had last been presented to IGARD on 7 February 2019, IGARD had been unable to make a recommendation in respect of the Genomics Medical Service as the relevant supporting documents were not available (the consent forms and patient information sheets). Accordingly, while this suite of documents and model may have been in use for some time, IGARD had **not** previously reviewed it and provided a formal recommendation. IGARD noted that the application, with the exception of the amendment to include GPDPPR data, had been previously approved via the SIRO precedent (not IGARD review) and that IGARD's review today was with regard to GPDPPR data only. IGARD noted and endorsed the specific points raised by PAG. In particular, IGARD queried the legal basis and how it related to the processing outlined in the application which appeared to indicate research beyond the National Health Service (Control of Patient Information Regulations) 2002 (COPI) regulation scope and suggested that the applicant work with NHS Digital to revise the consent materials to cover points previously raised by PAG and IGARD in order to establish a legal basis that covered the full scope of the proposed processing. In respect of the control cohort, IGARD suggested inserting a special condition in section 6 (Special Conditions), to clearly describe the control cohort and what can / cannot be undertaken with the control cohort, including that the control cohort **cannot** be analysed in isolation. Since the University of Edinburgh is the only onward recipient, as set out in the application, intellectual property (IP) / commercial is not relevant at this time, however this could be addressed further in the transparency and consent materials in due course. Noting the University of Edinburgh were the only onward recipient and COPI related to England and Wales only, IGARD asked that written confirmation be provided by NHS Digital's information governance (IG) that the legal basis for the Scottish University to have access to the pseudonymised data and specifically that a Scottish Data Controller is not precluded by the geographical restrictions of COPI from accessing the data originally gathered under that legal basis. In addition, that a copy of the IG advice be uploaded to NHS Digital's Customer Relationship Management (CRM) system as a future supporting document. IGARD were unclear as to the current and projected cohort size outlined in the application and supporting documentation provided as part of the review. Further clarity should be provided such as how many participants had been included now, how many were planned to be recruited in the future and section 5 (Purpose / Methods / Outputs) and the application updated accordingly. In addition, section 5(b) (Processing Activities) should be updated to clearly articulate at what point the processing of data would commence, for example, when a critical mass of participants had been reached, noting that approximately 3,000 participants had been recruited so far, with the aim to recruit 35,000 to the study.

	IGARD noted that the GP data for pandemic planning and research was a particularly rich dataset and contained a lot of diagnosis codes that may not be relevant, and asked that a clear justification be provided linking the datasets requested with the study purpose. Particular attention should be paid the significant size and scope of the GP data and that consideration should be given as to whether further data minimisation could be undertaken, for example by narrowing the diagnosis codes within the GP dataset. IGARD asked that section 5(a) (Objective for Processing) and throughout the application be updated to clearly articulate which aspects related to the COVID-19 purpose, which was relying on the COPI notice, since it was not clear. Of particular significance, it was noted that the description of the specific COVID-19 study, as set out in the protocol (with ethics approval) provided as a supporting document was **narrower** than that COVID-19 description provided in section 5 of the application. IGARD asked that section 5(d) (Benefits) and throughout the application be updated to clearly articulate what benefits would flow from this narrow COVID-19 study and they be clearly delineated from the other benefits in section 5(d). Noting that the applicant was using the 100,000 Genomes participants as a control cohort, to clarify if the GP data would also be flowing for the control cohort, since it was not clear in the application or supporting documentation provided. In addition, the applicant should clarify if the composition of the 100,000 Genomes control group was an appropriate control group for a study of this nature since many in the control group would have a rare disease or cancer. IGARD also queried what would happen if a participant was found to be in both the study group and the control group and if NHS Digital would filter out that participant and that clarification be sought. NHS Digital noted that a 'constant' identifier would be flowing back to the applicant from NHS Digital since not all the data was identifiable, however, IGARD asked that a clear rationale for the flow of identifiers back to Genomics England from NHS Digital be provided in section 5. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. NHS Digital confirmed that should the application be significantly updated it would be re-presented to PAG before re-submission to IGARD, otherwise it would come back to a BAU IGARD meeting. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation deferred, pending: 1. In respect of the specific points raised by PAG: a) To clearly describe the control cohort and address via the special condition in section 6, what can and cannot be undertaken with the control cohort (including that the control cohort cannot be analysed in isolation). b) NHS Digital IG to provide confirmation of the legal basis and how it relates to the processing outlined in the application which appears to indicate research beyond the COPI scope (and NHS Digital to work with the applicant to revise the consent materials to cover the points raised by both IGARD and PAG). c) Although IP / commercial is not relevant to this application (as University of Edinburgh is the only onward recipient), this could be addressed in the transparency and consent materials in due course.

	2. NHS Digital IG to provide confirmation of the legal basis for the University of Edinburgh to have access to the pseudonymised data and specifically that a Scottish Data Controller is not precluded by the geographical restrictions of COPI from accessing data originally gathered under that legal basis. 3. To update the application throughout to clarify the cohort size, for example, how many participants have been included now, how many are planned to be recruited in the future (including but not limited to) the reference to the size of the cohort described in section 5. 4. To be explicitly clear in section 5(a) and throughout the application which aspects relate to the COVID-19 purpose which is relying on the COPI notice, noting **the description of the specific COVID-19 study as set out in the Protocol (with ethics approval) is narrower than the COVID-19 description provided in section 5.** 5. To provide justification clearly linking the datasets requested with the study purpose and particular attention should be paid to the significant size and scope of the GP data, and whether further data minimisation could take place, for example, narrowing diagnosis codes etc. 6. To clarify if GP data is also flowing for the 100,000 Genomes Control Group. 7. To clarify if the composition of the 100,000 Genomes Control Group is an appropriate control group for a study of this nature, bearing in mind that many of the control group will have cancer or a rare disease. 8. To provide a rationale for the flow of identifiers back to Genomics England from NHS Digital. 9. To update the application throughout to be clear what benefits will flow from this narrow COVID-19 study. 10. To update section 5(b) to clarify at which point this data will start to be processed, for example, when a critical mass of participants has been reached. 11. To provide clarification of what will happen if a participant is in both the study group and the control group, and if NHS Digital will filter these participants. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment 2. IGARD suggested that this application would not be suitable for NHS Digital's precedent route
2.7	<u>University College London (UCL): Assessing the impact of the COVID-19 pandemic on vulnerable children: the DHSC-ECHILD-COVID study (Presenter: Kimberley Watson) NIC-381972-Q5F0V</u> **Application:** This was a new application for Civil Registration, Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS), for the purpose of a study looking at the impact of COVID-19 and lockdown on Children and young people (CYP) and whether there are any differences in the health and social effects of household confinement on vulnerable children and young people when compared to other CYP. CYP who are vulnerable due to social welfare or chronic health needs are expected to experience more adverse health and social effects of the COVID-19 lockdown than other CYP. Key concerns for services are the effects of household confinement during the COVID-19 lockdown, combined with the limited access to support from health, social care and education services. The researchers need to understand what impacts COVID-19 infection and related public health responses (such as lockdown) have had on CYP aged 25 years and under, to inform strategies for the current wave of infection, and any future waves.

NHS Digital noted that it was insufficiently clear in the application what was meant by 'vulnerable' and that a further explanation was required within the application.

Discussion: IGARD noted the update by NHS Digital and that further clarification should be provided, for the purpose of the application, exactly what 'vulnerable' definitions they were relying on since a number of differing definitions were in existence.

IGARD noted and supported this important and potentially valuable study with regard to the impact of COVID-19 and lockdown on CYP.

IGARD noted that under this application there would be a full cohort linking of the data to approximately 18 million CYP. Noting the NHS Digital standard for data minimisation and the General Data Protection Regulation (GDPR), IGARD asked that an appropriate justification be provided for this quantum of data and why less data, for example by way of a smaller geographical strata, would not suffice.

Noting that ethics approval was being fast tracked as per process, IGARD asked that a copy of the ethics approval specifically addressing the expanded purpose outlined in the application and supporting documentation be provided, and in addition that a copy be uploaded to NHS Digital's Customer Relationship Management (CRM) system as a future supporting document.

IGARD noted that a licence should be in place between UCL and the Department for Education and that a special condition had been inserted into section 6 (Special Conditions) addressing this, but that it should be updated to clearly reflect the expanded use and purpose outlined in the application. In addition since the licence expired on the 30 September 2019, any renewed licence should clearly cover the expanded purpose and cohort and evidence of the renewal should be provided and a copy held on the CRM system as a future supporting document.

IGARD suggested that the applicant may wish to consider engaging with further relevant interested patient and public groups and children and young people's charities. In addition, and given these groups have a geographical spread across England and Wales and the size of the cohort, if the applicant could have involved them at an earlier stage.

IGARD noted that section 3(c) (Patient Objections) in reference to the question 'patient objections applied' the answer of 'yes' had been given and that further clarity be provided on the national data opt-out statement made.

IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices.

IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route.

Outcome Summary: recommendation to approve subject to the following conditions:

1. In respect of the Licence which has expired:
    a) To provide evidence of the renewed Licence which clearly covers the expanded use purpose and cohort.
    b) To amend the Licence special condition in section 6, to reflect the expanded use and purpose.
2. In respect of the Ethics Approval:
    a) To provide a copy of the Ethics Approval specifically addressing the expanded purpose as described in the application and the expanded cohort.
    b) To upload a copy of the Ethics approval to NHS Digital's CRM system.
3. To provide an appropriate justification of why the full cohort linking the data of 18 million children and young people is required, and why less data, for example

	smaller geographical strata, won't suffice (refer to NHS Digital Data Minimisation Standard and GDPR). The following amendments were requested: 1. To clarify for the purpose of this application exactly what 'vulnerable' definitions they are relying on. 2. To provide clarity on the national data opt-out statement in section 3(c). The following advice was given: 1. IGARD suggested that the applicant may wish to consider engaging with relevant interested patient and public groups and children and young people's charities and suggest that these groups have a geographical spread across England and Wales, and given the size of the cohort if they could have been involved at an earlier stage. 2. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment 3. IGARD suggested that this application would not be suitable for NHS Digital's precedent route It was agreed the conditions would be approved OOC by IGARD Members.
2.8	Health Data Research UK: R14.2 - CVD-COVID-UK. Cardiovascular disease and COVID-19: using UKwide linked routine healthcare data to address the impact of cardiovascular disease on COVID-19 and the impact of COVID-19 on cardiovascular diseases. (Presenter: Garry Coleman) NIC-381078-Y9C5K **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), Emergency Care Data Set (ECDS), COVID-19 Second Generation Surveillance System (SGSS), Secondary Uses Service Payment by Results (SUS PBR) and Civil Registration data. The purpose is to establish a Cardiovascular Disease Trusted Research Environment (CVD TRE), to look at the effects of cardiovascular disease, and its risk factors and medications, on COVID-19 disease, also the direct and indirect impacts of COVID-19 on cardiovascular disease. The direct impacts include acute life-threatening complications, such as heart attacks, strokes and clots in the legs and lungs. In addition, since COVID-19 increases both inflammation and the risk of blood clots, there may be an increased risk of heart attack, stroke and other cardiovascular events in the medium and long term. **Discussion:** IGARD noted that aspects of this application had been previously seen by IGARD – NHS Digital COVID-19 Response meetings on the 26th May, 2nd June, 9th June and 16th June 2020. IGARD suggested that the TRE should have an independent oversight body and that such body should furnish NHS Digital, on a quarterly basis, a report detailing the projects that had been undertaken in the previous quarter. It was suggested that since the HDRUK have an independent oversight group, that they may wish for a patient representative of that group to be included on the oversight body to provide additional independent oversight. In addition NHS Digital may wish to consider whether, in the short term, they also should have representation on the oversight body. IGARD noted the update from NHS Digital with regard to the TRE but it was not clear how the consortium worked as a group of 17 Data Controllers and that Terms of Reference (ToR) be produced which addressed a number of key areas including the process for approving projects; who was responsible for the various activities carried out in the TRE; how the Data Controllers would work together and how the Data Controllers would share the responsibilities

(to satisfy Article 26 of the General Data Protection Regulation (GDPR)); the suitable checks and balances that should be in place, such as by way of detailing the composition of an oversight body; and how transparent minutes and records would be kept by the oversight body.

Noting that the TRE had limited data minimisation functionality, section 5 (Purpose / Methods / Outputs) should be updated to reflect that any project should wait until the functionality to minimise further was available, but should a project be urgent or not require data minimisation, that the consortium would rely on the interim data minimisation measures currently in place.

IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD noted that before the TRE started that each Data Controller outlined in the application should have in place a project specific privacy notice, and in order to reduce burden on each Data Controller suggested whether a privacy notice could be published on the HDRUK consortium website with each Data Controller linking back to this main privacy notice from their own website.

IGARD noted that section 2(c) (Territory of Use) was 'England and Wales' however since a number of the Data Controllers were based in Scotland (namely Universities of Dundee, Edinburgh and Glasgow) that the territory of use be expanded to include Scotland.

IGARD noted reference in section 3(b) (Additional Data Access Requested) and section 5(b) (Processing Activities) reference to '*future cardiovascular conditions*' and asked for an explanation.

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 subject to conditions until the 30th September 2020:

1. In respect of the TRE:
    a) To set up an independent oversight body.
    b) To produce a detailed Terms of Reference document which addresses:
        i. The process for approving projects.
        ii. Who is responsible for the various activities carried out in the TRE.
        iii. How the data controllers will work together and share responsibilities (to satisfy Article 26 of GDPR)
        iv. Suitable checks and balances (for instance the composition of the oversight body).
        v. How transparent minutes and records will be kept for the oversight body business.
    c) The independent oversight body furnishes NHS Digital with a report on a quarterly basis, detailing the projects undertaken.

The following amendments were requested:

1. To explain what is meant by *"future cardiac conditions"*.
2. To extend the territory of use to include Scotland.
3. With regard to the data minimisation techniques in the future, to update the application to state that if possible, the project should wait until that is available, however if the projects are urgent (or do not require data minimisation), that they will rely on the interim data minimisation measures.

The following advice was given:

1. IGARD supported NHS Digital's suggestion to have an NHS Digital representative on the independent oversight body, and queried whether an HDR UK patient

	representative may also want to be included on the group to provide additional independent oversight. 2. IGARD suggested that each Data Controller would need a project specific privacy notice, but that consideration be given as to whether the privacy notice be published on the HDR UK consortium website, with each Data controller linking back to this main privacy notice. 3. IGARD advised that they would wish to review this application again 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 It was agreed the conditions would be approved OOC by IGARD Members.
3	<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 COPI regulation urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 23rd June can be found attached to these minutes as Appendix C. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
4	<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.
5	<u>AOB:</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 19/06/20

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-196221-K4K3Y	The University of Manchester	21/05/2020	1. The applicant to confirm that they do not wish to include any other work packages as being work packages that benefit from the flow of data under this application, so as not to constrain themselves in the future use of this data by: a) Definitively describing which datasets are being used within this application; b) Provide confirmation that the applicant has reviewed the data requested and all the relevant work packages that will potentially need this data have been included within this application.	IGARD members	Quorum of IGARD members	N/A
NIC-64474-V4B2D	St George's, University of London	28/05/2020	1. To provide confirmation that the applicant's Privacy Notice is easily accessible to the wider public not just via the URL link provided in the application. 2. To update either the Privacy Notice or the application to address the discrepancy with regards to national Opt Outs since the Privacy Notice states Opt Outs **do** apply and section 3(c) states patient objections have **not** been applied.	IGARD members	Quorum of IGARD members	N/A

NIC-366210-V2H5M	Imperial College London	28/05/2020	1. In respect of the outputs and benefits (section 5c and 5d), and in light of the large amount of data requested, to provide: a) confirmation of who the key stakeholders are and how they will allow for the aspirations of this study to be met and to include details of any links, connections, channels and avenues available through these stakeholders; b) evidence of the specific historical benefits and yielded benefits in relation to healthcare; c) confirmation of how the additional COVID-19 purpose will provide a wider public benefit, or to provide justification of why this information is not currently available. 2. NHS Digital to provide written confirmation that the applicant has provided a GDPR compliant Privacy Notice, including (but not limited to) ensuring it is study specific and reflects the volume of data held / requested.	IGARD members	Condition 1 – Quorum of IGARD members. Condition 2 – IGARD Chair's action	*"Members did not provide unanimous contentment that condition 2 was met and so the Chair by way of 'chair's action' has taken the view with regard to condition 2 that although technically the condition could be seen to be met because NHS Digital provided written confirmation, the substance of the condition was not met since the information was spread over three separate privacy notices. IGARD would expect on renewal that a study specific easily accessible privacy notice be available."*
NIC-290527-P5C0Y	NorthWest EHealth Limited	11/06/2020	1. To provide an explanation as to what data MSD are accessing, where they are accessing the data from and for what reason; and that the application be updated accordingly; or if the application is correct, to update the privacy notice to accurately reflect what is happening.	IGARD members	Quorum of IGARD members	"IGARD have requested that in relation to the condition, the special condition in section 6 that states *"MSD will not have general access to the data for this application, and if access is required for audit purposes, that this will take place within Manchester University NHS Foundation Trust premises; and that no data will flow outside of England and Wales"* is updated accordingly to reflect that MSD will have no access to the data

						supplied by NHS digital for any purpose other than data received as aggregated with small numbers suppressed.”

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

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

- None notified to IGARD

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 17th June 2020

Application: DARS-NIC-374190-D0N1M V0.3
Organisation name: Genomics England
Profession Advisory Group Agenda item: 3

Areas of concern are:

1. Limitation of the study scope/design to COVID purposes as applies to GP Data.
2. Compatibility of the study design to the purpose and legal basis proposed to address common law (including the ability to withdraw) as applies to GP Data
3. The commercial use of data including retention of IP as applies to GP Data
4. Governance with respect to researcher subcontractor relations

1. Study Scope

The concerns about the study design: the application states the 100K genomic group is a control cohort, although later the applicant references "As of March 2020, the Genomics England Research Environment contained 107,694 genomes, of which, 33,461 were cancer and 74,233 were rare diseases." There was a concern that the control group was not appropriately described and / or would be analysed in isolation from the GENOMICC data.

NHS Digital should seek assurance that the appropriate Ethics approvals are in place for this study's COVID purpose.

The intervention arm has only recruited 3000 patients out of target of 35,000, which "could be up to one year of recruitment". Given sufficient patients are usually needed to power the studies this appears to be incompatible with the pandemic timelines and the breadth of data requested for COVID 19 (for example mental health, NHS111 data requests).

NHS Digital should work with the applicant to either define and limit the scope to COVID 19 (so data requested is proportionate and necessary or perhaps data requests are staged) or reassess the proposed approach and consider other legal basis for common law duty of confidence for the full scope of the research activity

2. Legal basis for common law duty

COPI Reg 3 (COVID19 purpose) is being used as the legal basis to set aside CLDoC, the group noted that the GenoMICC study purpose appears to indicate research beyond the current COPI scope.

Noting that participants are already partly consented, with particular reference to GP Data, the consent process must be explicit (and improved and checked to be sufficient, as noted in the document) and should cover the extent of data being disseminated to the TRE, those who will have access (including commercial companies and their claim to IP on the derived data) and that once participants have enrolled, should they withdraw their consent, their data will not be able to be removed, although (apparently) it will not be made accessible to researchers.

NHS Digital should work with the applicant to reconsider this legal basis and see if consent can be uplifted to align to the purpose and scope of data requested. NHS Digital should consider why withdrawal of data is technically not possible.

3. Commercial/IP

The Group would like NHS Digital & IGARD to be aware that publicly funded NHS Data is being used commercially, and the profits appear not to be returning to the NHS: “Companies own the IP of the derived data”. Professionally, BMA and RCGP consider NHS data and related algorithms to be a public good and thus derived data/algorithms be open-sourced; this also improves the clinical safety of algorithms.

4. Governance with respect to researcher subcontractor relations

The Group recommend NHS Digital ~~& IGARD~~ to consider if researchers/sub-contractors are joint data controller alongside GEL when accessing the data and make this clear in the application.

The Group noted the TRE model described appears secure (e.g. the airlock process) and support this approach, and would recommend that such privacy enhancing techniques are used more widely. Although PAG would also recommend GEL and NHS digital adopt pseudonymisation at source before data dissemination.

Attendees	**Role**	**Organisation**
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Julian Costello	GP	RCGP
Peter Short	Clinical Lead GP	NHS Digital
Pam Soorma	Secretariat	NHS Digital
Helen Buckels	Secretariat	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 23 June 2020

In attendance (IGARD Members):	Prof. Nicola Fear (Specialist Academic Member)
	Kirsty Irvine (Lay Chair)
	Dr. Geoffrey Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Gaynor Dalton (Information Governance) (Item: 2.1)
	Catherine Day (DARS (Observing)
	Louise Dunn (DARS)
	Liz Gaffney (DARS)
	Dickie Langley (Information Governance)
	Karen Myers (IGARD Secretariat) (Observing)
	Heather Pinches (DARS)
	Kimberley Watson (DARS) (Observing)
	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 DARS process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.
2.1	COVID-19 Vaccine Trials (no NIC reference available) IGARD welcomed the discussion about the proposed 'permission to contact' service for UK citizens and other current clinical trials which were ongoing as noted in both the UK Government's daily press briefings and associated news items on the BBC news website (or other news outlet website). IGARD members looked forward to receiving more detailed items to review in due course.
2.2	NIC-374190-D0N1M Genomics England

	Background: This was a verbal update to the application presented to the COVID-19 Response meeting on the 28 April, 5 May, 12 May and 16 June 2020. The GenOMICC (Genetics of Mortality in Critical Care) study aims to identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury. The application is to be presented to the business as usual (BAU) IGARD on Thursday 25 June 2020 for the inclusion of the GP Data for Pandemic Planning & Research. **IGARD Observations** There was reference to the consent and commercial model being based on the 100,000 Genomes Project, however IGARD noted, by way of background, that when this had last been presented to IGARD on 7 February 2019, IGARD had been unable to make a recommendation in respect of the Genomics Medical Service as the relevant supporting documents were not available (the consent forms and patient information sheets). Accordingly, while this form of suite of documents and model may have been in use for some time, IGARD had **not** previously reviewed it and provided a formal recommendation. IGARD noted that the application would be coming to this Thursday's BAU meeting with regard to the GPDPPR aspect and that this had been reviewed by the Profession Advisory Group (PAG) prior to its inclusion on an IGARD agenda, with a copy of their minute extract appended to IGARD's published minutes. IGARD noted the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday, but a follow up to points raised at last week's COVID-19 Response meeting and thanked NHS Digital for their verbal update. IGARD members noted that NHS Digital information governance (IG) had confirmed that the sublicence model only extended to the University of Edinburgh for the purposes of the GenoMICC study and would be accessing the data as set out in the study protocol. NHS Digital IG were content that the study was covered by the National Health Service (Control of Patient Information Regulations) 2002 (COPI) regulations, as University of Edinburgh was not handling data owed a duty of confidence (noting that any COPI legal basis only applied to England and Wales). IGARD suggested that this be formally documented and a copy of the IG written advice and analysis be uploaded to NHS Digital's customer relationship management (CRM) system as part of the supporting documentation pack.
2.3	<u>NIC-381078-Y9C5K Cardiovascular Disease Trusted Research Environment for British Heart Foundation (CVD TRE for BHF)</u> **Background:** This was a verbal update to an application presented to the COVID-19 Response meetings on the 26 May, 2 June, 9 June and 16 June 2020 to access data for COVID-19 purposes under a TRE. NHS Digital noted that the discussion today was about the mechanism to disseminate data, not the application which is to be presented to the business as usual (BAU) IGARD on Thursday 25 June 2020. **IGARD Observations:** NHS Digital noted that the TRE is fundamentally a secure environment and that it was about finding the right balance and controls either by way of putting in place an overarching

	agreement for specified programmes of work or by way of a precedent whereby individual projects would be approved by the SIRO. GP Data could flow under precedent, but only after careful review of such precedent and PAG would continue to be consulted on precedent requests. See: https://digital.nhs.uk/services/data-access-request-service-dars/gpes-data-process-for-assessing-requests. IGARD noted the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday, but a follow up to points raised at last week's COVID-19 Response meeting and thanked NHS Digital for their verbal update.
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.