Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 18th 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. 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
Dr. Imran Khan	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Victoria Byrne-Watts	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Mujiba Ejaz	Data Access Request Service (DARS) **(Observer 2.1 – 2.4)**
Karen Myers	IGARD Secretariat
Richard Hatton	Data Access Request Service (DARS) **(Observer 2.1 - 4)**
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 11th 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	NHS West Lancashire CCG: DSfC - NHS West Lancashire CCG IV, RS, Comm (Presenter: Duncan Easton) NIC-41605-Q7C3C **Application:** This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs) and e-Referral Service (eRS) data. It was also an amendment application to 1) add Microsoft as a Data Processor for Cloud storage; 2) to add Amazon Web Service as Data Processor for Cloud service; 3) to add NHS Fylde and Wyre CCG as a Data Processor; 4) to remove West Lancashire CCG as the Data Processor; 5) to remove Blackpool Teaching Hospitals NHS Foundation Trust; and 6) to add e-Referrals data for commissioning purposes. The 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. NHS Digital advised IGARD that the application would need updating throughout to reflect the role of Liaison Financial Service Ltd, noting that this information was omitted from the version that had been sent to IGARD for review. **Discussion:** IGARD noted and supported the update from NHS Digital in relation to updating the application to accurately reflect the role of Liaison Financial Service Ltd, using the previously agreed standard wording. IGARD queried if Liaison Financial Service Ltd would be receiving e-Referrals data since this data was not usually required for invoice validation and asked that confirmation was provided. If they were receiving the e-Referrals data, IGARD asked that a further justification of why, and how this fitted in with the processing activities was provided. IGARD noted in section 3(c) (Patient Objections Applied) that National Data Opt-outs were applied for identifiable data released for the purpose of Risk Stratification, and expressed concerns to NHS Digital that this would effectively remove patients receiving direct care who should not be removed. IGARD queried the Article 9 legal basis provided in section 3(b) (Additional Data Access Requested) for the e-Referral Service for Commissioning data, and asked that this was reviewed and either amended if appropriate, or that an explanation was provided as to why the legal basis stated was correct. In addition, IGARD also noted that it was not specifically clear within section 3(b) that the e-Referral Service for Commissioning was identifiable data, and asked that section 3(b) was updated to reflect this. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, and noted that their predecessor the Data Access Advisory Group (DAAG) had suggested a remedial action plan during a previous review of the

	application to resolve the ongoing issue(s) with the applicant's privacy notice. IGARD asked that clarification was provided of how this had been actioned. In addition, IGARD also asked that the privacy notice was updated to ensure further detail was provided on the profiling and / or any other automated decision making in relation to the Risk Stratification processing activities. IGARD noted the reference in section 5(a) (Objective for Processing) to *"users"* and asked that further clarification was provided of the professional roles of the users referenced. IGARD noted that throughout section 5(a) there was a number of repeated marketing type wording, and asked that this was revised to ensure that any such wording was only used once. IGARD queried the references in section 5(b) (Processing Activities) and section 5(c) (Specific Outputs Expected) to the NHS patient number being *"the only identifier"* and asked that this was amended to specifically state that this was **'the'** identifier. IGARD queried statements made within section 5(c), for example when referring to *"improving the quality of referrals"* and asked that this was reviewed to specifically revise any hyperbolic statements made. IGARD noted the yielded benefits had not been included within the application, and asked that section 5(d) (Benefits) iii (Yielded Benefits) was updated to reflect recent examples of yielded benefits and this applied to both renewal and templated applications to IGARD. IGARD noted the reference in section 5(a) and section 5(b) to *"role based access controls"* and asked that this was amended to address both role **and task** based access controls. IGARD queried information provided in section 1 (Abstract) in relation to Cloud computing, for example a reference to this having being assessed as "*class 4*", and were advised by NHS Digital that this had been included following an assessment by NHS Digital's Security Team. IGARD noted the updated from NHS Digital and asked that section 1 was updated to confirm that in respect of the Cloud computing, NHS Digital Security Team have assessed and were satisfied. A number of acronyms were noted in section 5 (Purpose / Methods / Outputs), and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use, be clearly defined and that it also had a further supportive explanation in language suitable for a lay reader. **Outcome Summary:** recommendation to defer, pending: 1. To update the application throughout to accurately reflect the role of Liaison Financial Service Ltd. 2. To provide confirmation if Liaison Financial Service Ltd are receiving the flow of e-Referrals data; and if so why and how this fit in with the processing activities. 3. In respect of the privacy notice: (a)To clarify how the remedial action plan previously set out by DAAG has been actioned. (b) To update to provide further details on the profiling and any other automated decision making in relation to the Risk Stratification processing activities. 4. To review the Article 9 legal basis provided for the e-Referral Service for Commissioning data; and either amend if appropriate, or provide an explanation as to why the legal basis stated is correct. 5. To provide further clarification in section 5(a) of the professional roles of the *"users"* referenced. 6. To revise section 5(a) to ensure that any marketing type wording is only used once.

	7. To amend the references in section 5(b) and section 5(c) to state that the NHS patient number is '**the'** identifier, instead of *"the only identifier"*. 8. To review the document throughout to review any hyperbolic statements made, for example *"improving the quality of referrals"* in section 5(c). 9. To complete the yielded benefits in section 5(d) (iii) with relevant examples. 10. To update section 3(b) to reflect that the e-Referral Service for Commissioning data is identifiable. 11. To amend the reference to controls in section 5(a) and 5(b) to address both role **and task** based access control. 12. To update section 1 with the standard wording to confirm that in respect of the Cloud computing, NHS Digital Security Team have assessed and are satisfied. 13. 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.
2.2	<u>NHS Blood and Transplant: A multi-centre, randomised, controlled trial evaluating the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage requiring major haemorrhage protocol (MHP) activation. CRYOSTAT2- Application to access 1 year mortality data for recruited patients (Presenter: Kimberley Watson) NIC-114652-L3R2T</u> **Application:** This was a new application for identifiable Civil Registration data, for the purpose of a study to evaluate the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage, particularly to understand if it reduces mortality. Fibrinogen acts as the 'glue' which holds a blood clot together and at low levels, blood clots don't form properly, and bleeding can continue. Cryoprecipitate is a frozen blood component prepared from plasma and rich in fibrinogen, by transfusing a high dose of cryoprecipitate early to replace fibrinogen levels in bleeding trauma patients it is believed that blood clots will be more stable and reduce bleeding. The cohort within this application consent to have their health status followed up for up to 12 months post injury. NHS Digital advised that this application was for those participants who had consented, and was linked to NIC-365492-H6D6V (item 2.3) where s251 was relied upon to set aside the Common Law Duty of Confidentiality. **Discussion:** IGARD welcomed and supported the application and noted the importance of the study. IGARD discussed the consent materials provided and agreed with NHS Digital's analysis that the processing within the application was not incompatible with the consent and was likely to be within the reasonable expectations of those that had consented. In addition, IGARD also noted and commended the trial completion newsletter that surviving study participants would receive, summarising the main results of the trial, and advised that was an excellent and proactive approach and should be used more widely. IGARD queried if the consent enabled the required flows of patient data if they were obtaining the final mortality data after 12-months has elapsed since the recruitment to the trial. IGARD noted the reference within the application to the US study and asked that further information was provided on this, specifically confirmation of the interplay between the study outlined in this application and the US study. In addition, IGARD also asked that section 5 (Purpose / Methods / Outputs) was updated to make it explicitly clear that NHS Digital data was not being shared and that the territory of use was England and Wales. IGARD queried the information outlining the transfer of data between the different processing locations for the data management and statistics limbs of the data processing since it was not

clear if they were standalone sites with data flowing between each site. Linked to this, IGARD asked that confirmation was provided confirming why NHS digital data was being requested on a quarterly basis, rather than once per year; and how the NHS Digital data was being transferred and managed across both sites.

IGARD noted the reference within the Patient Information Sheet(s) provided that stated *"We would like to continue to monitor you for safety",* and asked that a further explanation of this was provided, noting that this may cause undue alarm for participants.

IGARD queried how long the applicant would hold the NHS Digital data for, noting the conflicting information between the application and the supporting documents provided, and asked that the application was updated clarifying how long data would be held for and to ensure consistency as outlined within the consent materials.

IGARD noted the information in section 5(d) (Benefits) in relation to the clinical guidelines and asked that the statement on the applicants was updated to state *"The applicants have **involvement and experience** of developing guidelines".* In addition, IGARD also noted the statement within this section that stated *"findings from the study **will** also have an impact…"*, and asked that this was amended to state they ***"may"*** have an impact.

IGARD noted the information provided in supporting document 5.1, the study protocol, that outlined the process that would be followed when the patient(s) regains capacity and are able to provide consent to take part in the study, and asked that section 5 was amended to reflect this information.

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

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

1. In respect of the US study:
   a) To provide confirmation of the interplay between this study and the US study.
   b) To make it explicitly clear within section 5 of the application that NHS Digital data is not being shared and that the territory of use is England and Wales.
2. In respect of the transfer of data between the different processing locations for the data management and statistics limbs of the data processing:
   a) To confirm why NHS Digital data is requested on a quarterly basis.
   b) How is the NHS Digital data being transferred.
3. To provide a further explanation of the statement in the Patient Information Sheet, that states *"We would like to continue to monitor you for safety"*.
4. To ensure that the consent enables the required flows of patient data if they are obtaining the final mortality data after 12-months has elapsed since the recruitment to the trial.

The following amendments were requested:

1. To update the clinical guidelines statement in section 5(d) to state that "*The applicants have **involvement and experience** of developing guidelines"*.
2. To update the statement in section 5(d) to accurately reflect that the *"findings from the study **may** also have an impact…"*.
3. To amend section 5 to reflect the information provided in the protocol of the process that will be followed when the patient(s) regains capacity and are able to provide consent to take part in the study.
4. To update the application to clarify how long the applicant will hold the NHS Digital data for and as outlined within the consent materials.

2.3	NHS Blood and Transplant: A multi-centre, randomised, controlled trial evaluating the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage requiring major haemorrhage protocol (MHP) activation. CRYOSTAT2- Application to access 1 year mortality data for recruited patients (Presenter: Kimberley Watson) NIC-365492-H6D6V **Application:** This was a new application for identifiable Civil Registration data, for the purpose of a study to evaluate the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage, particularly to understand if it reduces mortality. Fibrinogen acts as the 'glue' which holds a blood clot together and at low levels, blood clots don't form properly, and bleeding can continue. Cryoprecipitate is a frozen blood component prepared from plasma and rich in fibrinogen, by transfusing a high dose of cryoprecipitate early to replace fibrinogen levels in bleeding trauma patients it is believed that blood clots will be more stable and reduce bleeding. The cohort within this application is a subgroup of participants who have not provided informed consent for a number of reasons. NHS Digital advised that this application was for those participants where s251 was relied upon to set aside the Common Law Duty of Confidentiality, and was linked to NIC-114652-L3R2T (item 2.2) where participants had consented. **Discussion:** IGARD welcomed and supported the application and noted the importance of the study. IGARD had a lengthy discussion on the s251 support, and noted the list outlining the categories of patients where s251 support would apply within section 1 (Abstract) and section 5(a) (Objective for Processing), and asked that quantitative data for these categories was provided, for example the numbers of patients allocated to various categories or numbers per Trauma Centre. In addition, IGARD also asked that it was clearly articulated what objective criteria was applied to ensure the appropriate and consistent use of the s251 support; and to clarify that all efforts had been taken to obtain informed consent before applying the s251 support. IGARD also queried who made the judgement on the subjective criteria and what checks and balances were undertaken when relying on the subjective criteria, for example, to ascertain whether a patient could be classed as *"distressed"*, and asked that section 5 (Purpose / Methods / Outputs) was updated to provide further information. IGARD suggested that the applicant may wish to consider taking appropriate steps to widen the access to those groups covered by s251 and whether in due course consent could be relied on for a wider range of participants. IGARD noted the reference within the application to the US study and asked that further information was provided on this, specifically confirmation and a clear description of the interplay between the study outlined in this application and the US study. In addition, IGARD also asked that section 5 was updated to make it explicitly clear, that NHS Digital data was not being shared, and that the territory of use was England and Wales. IGARD queried how long the applicant would hold the NHS Digital data for, noting the conflicting information between the application and the supporting document's provided, and asked that the application was updated clarifying how long data would be held for and to ensure consistency as outlined within the consent materials. IGARD noted the statement in section 5(d) (Benefits) that stated *"findings from the study **will** also have an impact…"*, and asked that this was amended to state they ***"may"*** have an impact.

	IGARD noted the statement in supporting document 8.8, the Health Research Authority Confidentiality Advisory Group (HRA CAG) form that stated *"Once section 251 approval is in place, a full Data Protection Impact Assessment (DPIA) will be completed…"*, and asked that a copy of the DPIA was uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide any quantitative data available for the numerous categories of s251 support, for example numbers of patients allocated to various categories or numbers per Trauma Centre. 2. To clearly articulate what objective criteria is applied to ensure the appropriate and consistent use of the s251 support; and to clarify that all efforts have been taken to obtain informed consent before applying s251. 3. To update section 5 to provide further information of who makes the judgement on subjective criteria and what checks and balances are undertaken when relying on subjective criteria (for example, to ascertain whether a patient could be classed as *"distressed".* 4. In respect of the US study: a) To provide confirmation and a clear description of the interplay between this study and the US study. b) To make it explicitly clear within the application that NHS Digital data is not being shared and the territory of use is England and Wales. The following amendments were requested: 1. To update the application to clarify how long the applicant will hold the NHS Digital data for and as outlined within the consent materials. 2. To upload a copy of the Data Protection Impact Assessment as a supporting document on NHS Digital's CRM system. 3. To update the statement in section 5(d) to accurately reflect that the *"finding from the study **may** also have an impact…"*. The following advice was given: 1. IGARD suggested that the applicant may wish to consider taking appropriate steps to widen the access to those groups covered by s251 and whether in due course consent could be relied on for a wider range of participants. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.4	<u>University College London: MR1470 - Using routine data to identify and assess clinical outcomes for the STAMPEDE trial: Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy. (Presenter: Kimberley Watson) NIC-59873-D8C6G</u> **Application:** This was a new application for pseudonymised Demographics, Cancer Registration, and Civil Registration Data, for the purpose of a project to assess novel approaches for the treatment of men with prostate cancer who are starting long-term Androgen Deprivation Therapy (ADT). Open since October 2005, and with over 13,000 men recruited, this Multi-Arm-Multi-Stage (MAMS) trial is the largest study of treatments for prostate cancer in the world, and is currently recruiting to three arms: 1) Standard of Care (SOC, arm A), 2) SOC with Metformin (arm K), and 3) SOC with Transdermal oestradiol (arm L).

	The application was been previously considered on the 9th August 2018 when IGARD had deferred pending: to explicitly state within section 5(b) that there will not be any access to the data by any third parties; to update the abstract to amend references to patient consent and the common law duty of confidentiality to: "*NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented*"; to update section 4 with the standard wording "*All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month*"; to provide evidence of clarification of the scope of the ethics approval; to update the legal basis within the data flow diagram in supporting document 1; the application should be updated to clarify that University College London are a Data Controller who also processes data; the applicant might consider seeking section 251 support to cover all participants or, if practicable, to update the consent material and go back to the cohort; NHS Digital might consider liaising with CAG in respect of the general principles raised by the consent materials. . **Discussion:** IGARD noted that the application had been updated to reflect all of the comments previously made, however noted, that in respect of the previous IGARD deferral point 4, the reference within the application to the ethics amendment approval supporting document needed amending to reflect supporting document 2.3 and **not** 2.2. IGARD also noted and commended the patient letters and the use of the two patient representatives as referenced within the application. IGARD noted the application reflected the data flows and were not querying the legal basis within section 1 (Abstract) but queried why the full date of death remained after pseudonymisation and asked that justification was provided of this; and in addition, what significance there was in keeping this potential identifier in the data set will bring to the outputs, and what real world benefits will accrue to patients by doing so. IGARD noted that there was no information within the application as to what had happened with this application since it's last submission to IGARD in 2018, and asked that section 1 was updated to provide a full approvals history narrative of the application. IGARD queried how, noting that that there were over 13,000 men recruited to the study, the **results would be** widely disseminated to the cohort and interested general public, and asked that section 5(c) (Specific Outputs Expected) was updated with further details. IGARD queried the information provided in section 3(b) (Additional Data Access Requested) that stated the data requested was pseudo-anonymised, and queried if this was correct, noting that the Study ID would be sent with the datasets to the applicant, and asked that a further explanation was provided. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To provide justification of why the full date of death remains after pseudonymisation; what significance keeping this potential identifier in the data set this will bring to the outputs and what real world benefits will accrue to patients by doing so. The following amendments were requested: 1. To update section 1 to provide a full approvals history narrative of the application following its last submission to IGARD in 2018. 2. In respect of the previous IGARD deferral point 4, to update the reference to the ethics amendment approval supporting document 2.3 (**not** 2.2).

	3. To update section 5(c) to provide further details of how there will be a wider dissemination to the cohort and interested general public. 4. To provide a further explanation as to why the table in 3(b) states the data is pseudo-anonymised rather than identifiable. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.5	<u>London School of Economics and Political Science: DETERMIND: DETERMinants of quality of life, care and costs, and consequences of INequalities in people with Dementia and their family carers. NHS Digital data-linkage (mortality data) request. (Presenter: Frances Hancox) NIC-258494-J2Q5M</u> **Application:** This was a new application for pseudonymised Civil Registration data, for the purpose of a study, which includes 7 separate workstreams, from a cohort of 900 participants with a recent diagnosis of dementia and their carers (total = 1800). The objective is to provide a range of quantitative and qualitative evidence, interpreted using a theory of change framework, about inequalities in experiences, outcomes and costs following a diagnosis of dementia. **Discussion:** IGARD had a lengthy discussion regarding the consent aspects of the application. It was queried how the consultee declaration form addressed the Common Law Duty of Confidentiality and enabled NHS Digital to release relevant data. IGARD noted that information which is owed a duty of confidence required consent before release. In the absence of individual consent, an LPA for health and welfare, a Court Protection Deputyship or s251 support is required. Consultee advice is not sufficient. However, this is a complex area. IGARD queried the data flows described in the application, in particular whether the data flowed back to the University of Sussex and then on to the Trusts, or by way of another arrangement, and asked that confirmation was provided that the NHS Digital data flowed as described reflected what would be happening in fact. IGARD queried the statement in section 1 (Abstract) "*The role of research partners at the University of Cambridge is to provide expert advice…*" and asked that further clarification was provided on what the University of Cambridge was providing expertise on. IGARD noted that the Data Controllers privacy notice was currently available via the University of Sussex website and asked that a link was added via all participating Trust website for ease of accessibility and transparency. IGARD queried the ethical information statement within section 5(a) (Objective for Processing) that stated *"All ethical issues associated with processing of the data have been comprehensively addressed in HRA REC approvals."* and asked that this was replaced with *"Possible ethical issues have been considered and addressed throughout the process, including those considered by the HRA REC approval process."* IGARD noted and endorsed NHS Digital's review that the applicant did not meet NHS Digital's Standard for privacy notices. **Outcome Summary:** recommendation to approve for all those members of the cohort who are carers or patients who are relying on the consultee declaration forms **with** the additional limbs of support (as set out in point 1 below). 1. In respect of the consultee declaration form to provide clarification of how the common law duty of confidentiality will be addressed, whether by lasting power of attorney (LPA) for health and welfare, Court of Protection Deputyship or s251 support.

	2. To confirm that the NHS Digital data flows as described in the application reflect what is happening in fact, in particular whether the data flows back to the University of Sussex and then on to the Trusts, or another arrangement. 3. To provide further clarification in section 1 what the University of Cambridge will be providing expertise on. 4. To add a link to the Data Controller's privacy notice via all participating Trust websites. 5. To replace the existing ethical information provided in section 5(a) with the following statement *"Possible ethical issues have been considered and addressed throughout the process, including those considered by the HRA REC approval process."* **Outcome Summary:** unable to recommend for those members of the cohort relying on the consultee declaration forms **without** any additional limbs of support to cover the duty of confidentiality (namely LPA, Court of Protection Deputyship or s251 support).
2.6	<u>Sandwell and West Birmingham Hospitals NHS Trust: Birmingham and Black Country Atrial fibrillation cohort study follow up (Presenter: Louise Dunn) NIC-331733-T2K1Z</u> **Application:** This was a new application for identifiable Medical Research Information Service (MRIS) data, for the purpose of a prospective longitudinal observation study, aiming to improve understanding of Atrial Fibrillation (AF). AF is a condition affecting 3% of the population in which the heart rate becomes irregular and in some cases is very fast, a complication of AF is heart failure. This application previously came to IGARD on the 23rd April 2020 for advice on the consent related materials, where IGARD made a number of observations and suggestions for further consideration. NHS Digital advised that following IGARD's advice on the consent materials, further discussions had taken place with the applicant, and the application had been amended accordingly and that this was reflected in the application. **Discussion:** IGARD welcomed and supported the application and noted the importance of the study. IGARD also noted the update from NHS Digital in relation to the amendments to the application following the advice on the 23rd April 2020. In addition, IGARD commended the applicant for regularly inviting patients who were treated at Sandwell and West Birmingham Hospitals NHS Trust to attend AF meetings, which were designed to update patients on new developments in the diagnosis and treatment of AF and relevant developments in local AF services. IGARD noted within supporting document 2,2, version 7 of the patient information sheet, the statement that *"The study is being funded by the European Union."* and asked that the applicant complete and provide a copy of the EU funding form that was available via NHS Digital's website. In addition, IGARD asked that this form, was also uploaded to NHS Digital's Customer Relationship Management (CRM) system and that following receipt of the completed EU funding form, the application was reviewed and amended as necessary pending the answers provided. IGARD noted the yielded benefits had not been included within the application, and asked that section 5(d) (Benefits) iii (Yielded Benefits) was updated with some of the yielded benefits that had been achieved to date and as outlined in section 5(c). IGARD queried some of the statements within section 5 (Purpose / Methods / Outputs), for example "*As AF currently affects 3% of the population and the cost of treating this condition and its complications accounts for 3% of the NHS budget…*" and asked that this was amended

	to ensure the focus of the study was on the impact and benefit to patients and not the cost implications first. IGARD noted that there was conflicting information throughout the application as to whether linkage of NHS Digital's data was taking place, and asked that confirmation was provided of what linkage is taking place, where and with what datasets. **Outcome Summary:** recommendation to approve subject to the following condition: 1. The applicant to complete and provide a copy of the EU Funding Form via the NHS Digital website. The following amendments were requested: 1. NHS Digital to upload the completed form on to their CRM system. 2. Following receipt of the completed EU funding form, to amend the application as necessary pending the answers provided. 3. To update section 5(d) (iii) with some of the yielded benefits flowing with what has been achieved to date. 4. To amend section 5 to ensure the focus of the study is on the impact and benefit to the patients and not the cost implications first. 5. To provide confirmation of what linkage is taking place, where and with what datasets. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD Chair.
2.7	<u>LA-SER Europe Ltd: Clinical Characteristics of Adult Haematological Cancer Patients with Veno-Occlusive Disease and Their Health Resource Utilisation and Cost Burden in England (Presenter: Louise Dunn) NIC-301834-K0S2Y</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registration data, for the purpose of a study, which will assist in obtaining valuable information on haematological cancer patients, especially those with leukaemia, who developed veno-occlusive disease (VOD), which is a rare but serious disorder of the liver. The Primary Objective of the study is to 1) describe the demographic and clinical characteristics of haematological cancer patients who developed VOD by applying an algorithm using ICD-10 codes, adapted Baltimore and Seattle and other clinical criteria for diagnosis of VOD among haematological cancers; and the secondary objectives are to 1) describe the mortality rate among haematological cancer patients with VOD; and 2) to describe the resource utilisation and cost burden for haematological cancer patients who developed VOD. NHS Digital advised IGARD that section 5 (Purpose / Methods / Outputs) would need updating to reflect that the funder would not have influence on the outcomes nor suppress any of the findings of the research. **Discussion:** IGARD welcomed and supported the application and noted the importance of the study; and commended the applicant for ensuring anyone in the public domain would be able to access the journal article(s) as a result of this study. IGARD noted and supported the update outlined by NHS Digital in section 5, stating that the funder would not have influence on the outcomes nor suppress any of the findings of the research. IGARD discussed the complicated clinical and scientific aspects of the study and given the volume of data requested, the stated projected aims and the nature of the rare disease, asked that a clear case was set out within the application confirming that there was sufficient expertise and appropriate data available to enable the design of an algorithm, which was relevant to the UK health environment. In addition, that clarification was provided as to whether the study should involve a hepatologist alongside the haematologist and if the

	haematologist was able to carry out the stated work with only aggregated data with small numbers suppressed and asked that this was clarified. In addition, IGARD also queried how the study would validate the algorithm when there was currently no 'gold standard' for diagnosis of this very rare disease, and asked for further clarity. IGARD noted the statement in section 5(a) "*Such algorithms were previously applied using MarketScan and Medicare data in the USA…*" and asked that confirmation was provided as to whether the study was adapting a USA algorithm for UK use, or developing a novel algorithm for UK use, and to consistently describe this throughout the application. IGARD queried what benefits would accrue from this study, in particular for the applicant and funder, and asked that section 5 was updated to accurately describe **all** the **potential** benefits accruing to both the applicant and the funder. In addition to the direct benefits, to transparently outline any potential declarations of interest or indirect benefits that may accrue now or in the future to either the applicant or funder. IGARD noted the statement in section 5(b) (Processing Activities) "*Access is limited to substantive employees of Analytica Laser who will be physically located in the London office…*" and queried if, due to the current pandemic and the large volume and sensitivity of the data requested, that consideration was given to whether storing the data on one laptop in a London based office was a practical solution, particularly with potential home working. In addition, IGARD asked that written confirmation was provided stating that home working was permitted under this Data Sharing Agreement (DSA). IGARD queried how the results of the study would be made public, and asked that a special condition was inserted in section 6 (Special Conditions) that all the results would be made public simultaneously with outputs distributed to funder. IGARD noted that section 3(b) (Additional Data Access Requested) did not reflect that every data entry should refer to data being filtered by the ICD10 code, and asked that the data minimisation columns were updated to reflect this. In addition, IGARD also asked that section 5 was updated to provide a clear explanation of approximately how many patients would be covered by the filtering of ICD10 codes. IGARD noted that the application indicated that other data was being fed into the study, and asked that confirmation was provided of where the applicant was accessing this data from. IGARD noted that the disease outlined within the application was a very rare complication in the UK and not a high cost issue per se, and asked that application should be reviewed to make clear what the outputs are, and the benefits that would accrue to health and social care in England and Wales, and how they are proportionate to the data being obtained and processed. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, and suggested that the applicant should work with NHS Digital on a Privacy Notice that is General Data Protection Regulation (GDPR) compliant and that no data would flow until such time as a GDPR-compliant Privacy Notice, as assessed by NHS Digital, had been published; which relates to the specific processing as set out in this DSA. **Outcome Summary:** recommendation deferred pending: 1. Given the complicated clinical and scientific aspects of the study and given the volume of data requested, stated projected aims, the nature of the rare disease:

	a) To set out a clear case that there is sufficient expertise and appropriate data available to enable the design of an algorithm, which is relevant to the UK health environment. b) To clarify whether the study should involve an hepatologist alongside the haematologist. c) To clarify that the haematologist is able to carry out the stated work with only aggregated data with small numbers suppressed. d) To clarify how the study will validate the algorithm when there is currently no 'gold standard' for diagnosis of this very rare disease. 2. To accurately describe within section 5 **all** the **potential** benefits accruing to both the applicant and the funder and in addition to direct benefits, to transparently outline any potential declarations of interest or indirect benefits that may accrue now or in the future to either the applicant or funder. 3. To confirm if the study is adapting a USA algorithm for UK use, or developing a novel algorithm for UK use, and to consistently describe this throughout the application. 4. Due to the current pandemic and the large volume and sensitivity of the data requested: a) To consider whether storing this data on one laptop in a London based office is a practical solution, particularly with potential home working. b) To provide written confirmation that home working is permitted under this DSA. 5. To insert a special condition in section 6 that all the results will be made public simultaneously with outputs distributed to funder. 6. To update the current wording in section 5 to state that the funder will not have influence on the outcomes nor suppress any of the findings of the research. 7. To update the data minimisation columns in section 3b to accurately reflect that every data entry should refer to data being filtered by ICD10 code. 8. To clearly explain in section 5 approximately how many patients will be covered by the filtering of ICD10 codes. 9. Since it appears other data is being fed into the study, to confirm where the applicant is accessing this data from. 10. The disease outlined in the application is a very rare complication in the UK and not a high cost issue per se: the application should be reviewed to make clear what the outputs are and the benefits that would accrue to health and social care in England and Wales, and how they are proportionate to the data being obtained and processed. 11. The applicant should work with NHS Digital on a Privacy Notice that is GDPR compliant and that no data will flow until such time as a GDPR-compliant Privacy Notice, as assessed by NHS Digital, has been published; which relates to the specific processing as set out in this DSA.
3	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-135277-R8M3G Regional Drug & Therapeutics Centre Newcastle • NIC-90070-F3K4Z The Health Foundation IGARD welcomed the two applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the

	oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and 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 16th June can be found attached to these minutes as Appendix B. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
5	<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 12/06/20

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-309029-P7H1D -	London School of Economics (LSE)	28/05/2020	1. NHS Digital to provide written confirmation that the applicant has reviewed the published Privacy Notice including (but not limited to) ensuring there are no misleading statements and ensuring that it is clear that data opt out will not apply as the data is pseudonymised data.	IGARD Alternate Deputy Chair	OOC by IGARD Alternate Deputy Chair	

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

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

- None notified to IGARD

Appendix B

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 16 June 2020

In attendance (IGARD Members):	Paul Affleck (Specialist Ethics Member)
	Kirsty Irvine (Lay Chair)
	Dr. Geoffrey Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Vicky Byrnes-Watts (DARS)
	Garry Coleman (DARS) (Item: 3)
	Catherine Day (DARS)
	Louise Dunn (DARS)
	Liz Gaffney (DARS) (Item: 3)
	Fran Hancox (DARS)
	Dickie Langley (Information Governance) (Item: 2.2)
	Karen Myers (IGARD Secretariat) (Observing)
	Kimberley Watson (DARS)
	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:** There were no declarations of interest.
2.1	NIC-374190-D0N1M Genomics England **Background:** This was an update to the application presented to the COVID-19 Response meeting on the 28 April, 5 May and 12 May 2020. The GenOMICC (Genetics of Mortality in Critical Care) study aims to identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury. NHS Digital noted that the application would be approved under SIRO precedent for the COVID-19 work being undertaken as part of this application, but that the application

	amendment in relation to GP Data for Pandemic Planning and Research (GPDPPR) would come to a future Thursday BAU meeting for a recommendation. **IGARD Observations** NHS Digital summarised their most recent discussions with the applicant, including; the amount of data requested, that they had potentially identified a new Data Processor: Lifebit Biotech and that previous feedback with regard to the consent materials were the subject of ongoing discussions. IGARD members queried why the application would go down the SIRO precedent and noted that for such a high-profile applicant / application that NHS Digital may also wish for the assurance of an independent review via the Thursday business as usual (BAU) IGARD meeting. IGARD noted that the application would be coming to a Thursday BAU meeting with regard to the GPDPPR only and that this would also be reviewed by the Profession Advisory Group (PAG) prior to its inclusion on an IGARD agenda. IGARD members noted that the applicant was planning to sub-licence following the 100,000 Genomes model, however that arrangement was via participant consent and for this application the legal basis was National Health Service (Control of Patient Information Regulations) 2002 (COPI) regulations. IGARD suggested that NHS Digital should consider whether the emergency powers under the COPI Regulation 3, which "*makes provision for the processing of patient information for the recognition, control and prevention of communicable disease and other risks to public health*", allowed for the sub-licencing of data to researchers. IGARD queried where there would be analysis and record keeping of how sub-licensees met the requirements of Reg 3(3)(b) of COPI. If NHS Digital's IG had assessed this element as part of their review, that a statement of that fact should be included within section 5 of the application. IGARD members also raised a query with regard to the type and amount of data requested under this application, in particular, and not limited to, the request for the mental health services dataset and again suggested that consideration be given as to whether this was for a COVID-related purpose, in terms of the restrictions set out in Reg 3(1) COPI, and that this analysis of the data, which may have already been reviewed by NHS Digital's IG, should be included in section 5 of the application. IGARD members noted that the applicant had published information on their website and that they may wish to expand this information to include a register of the sub-licensees to address transparency surrounding such things as who was accessing the data and for what purpose under a sub-licence agreement. As previously discussed, IGARD members noted that the key issues with regard to the consent form and patient information sheets provided was to ensure that NHS Digital were clearly referenced, that reference was made to identifying data flowing to and from NHS Digital, and to ensure that no inadvertent barrier was put in place in current documentation that would stop any sub licencing or onward sharing. IGARD members also noted that the Protocol v2.1 which had been provided as a supporting document referenced under '*informed consent – patients unable to consent for themselves*' that if a patient was unable to consent for themselves due to being seriously ill that a patient representative (friend or relative) may be given the option of consenting immediately as

	appropriate for the local legal requirements, however IGARD members noted that for adults only, it should be via a lasting power of attorney (LPA), specifically for health and social care. With reference to the potential new Data Processor identified by NHS Digital, IGARD members supported NHS Digital's analysis that more work should be undertaken with NHS Digital's security team and that until such time Lifebit BioTech should not be included as a Data Processor in this application. In addition, IGARD members noted the importance of the applicant updating their privacy notice. It was agreed that when the application came to a Thursday BAU meeting for a full review, IGARD members would expect to see an indicative timeframe with regard to how the applicant was planning to update their privacy notice, since this was such an important and far reaching project. IGARD members noted that when the application and supporting documents are submitted for review that the documentation's resolution is updated since it was difficult at times to read a number of the colour coded supporting documents
2.2	NIC-381078-Y9C5K Cardiovascular Disease Trusted Research Environment for British Heart Foundation (CVD TRE for BHF) **Background:** This application to access data for COVID-19 purposes under a TRE had previously been discussed at the COVID-19 response meetings on 26 May, 2 June and 9 June 2020. NHS Digital noted that the application had been updated to reflect previous comments received. **IGARD Observations:** NHS Digital noted that currently the TRE did not have the functionality to minimise the data to project level, it could only be minimised at programme level with access for the purposes outlined in the Data Sharing Agreement (DSA), but that work was ongoing to add this functionality to future TREs. However, IGARD members noted that there were currently 17 Data Controllers listed within the application (with potential for further access by additional researchers) and that NHS Digital should give consideration as to whether they were all fulfilling that role and whether some could be considered as Data Processors. IGARD also queried whether some preliminary processing within the TRE could be undertaken and shared with the parties to minimise handling of the data and duplication of effort. NHS Digital suggested that a specific Data Protection Impact Assessment (DPIA) be undertaken to understand further the roles, structure, controls, processing and approach undertaken for this TRE and IGARD members were in agreement with this approach. Noting that Health Data Research UK (HDRUK) had an active programme of engagement with patients and the public, IGARD members suggested that the applicant involves patients and the public effectively and ensures that a public facing webpage was available and covered the CVD TRE. Particularly in light of the on-going data minimisation discussions, IGARD members asked that a verbal update be given at next week's COVID-19 response meeting.
2.3	NIC-378456-W5F0Z University of Birmingham

	Background: The Birmingham Coronavirus and minority ethnic (BRUM) study's aim was to look at the association between ethnicity and incidence of, or adverse health outcome due to, COVID-19 with the critical need to distinguish between innate susceptibility, co-existing burden of health disease or socioeconomic, lifestyle and environmental factors, linking data from Birmingham City Council to nationally captured datasets. NHS Digital noted that this study had received the Health Data Research UK (HDRUK) prioritisation and that a copy of the draft study protocol had been provided for early comment. **IGARD Observations:** IGARD members noted that this was an incredibly important and potentially complex study into a link between ethnicity and COVID-19 outcomes and suggested that the applicant may wish to investigate what other research is being undertaken or is about to be undertaken in this field and collaborate or pool expertise, if possible. Noting that research utilising ethnicity categorisation is sometimes difficult because of the inconsistent mix in terminology, the applicant may also wish to seek out collaboration with another academic with experience in this field and, in particular, suggested support from an epidemiologist. In addition, and noting that linking to data held by Birmingham City Council made this an incredibly rich source of identifiable data, the applicant should consider the data linkages and processes being undertaken as part of any future application. IGARD members noted reference to the Race Equality Foundation providing project oversight and support to the study, however, to ensure an impartial oversight, suggested that the Race Equality Foundation provide advice and support, rather than *"oversight"* which should come from a scientific body. IGARD members looked forward to receiving more information as the study progressed and were available to support the application at future meetings.
2.4	<u>National Institute for Health Research Inflammatory Bowel Disease (NIHR IBD) BioResearch (no NIC reference available)</u> **Background:** This item had previously been discussed at the COVID-19 response meeting on the 2 June and 9 June 2020. IGARD had requested an update with regard to the applicant's response to providing a copy of the honorary contract under the research passport. **IGARD Observations:** NHS Digital noted that the applicant had provided example copies of the honorary contracts as listed on the Health Research Authority (HRA) website. IGARD reiterated their previous comments that although supportive of the Research Passport system, the example honorary contract provided, which would flow from the Research Passport, did not, for example, provide for the usual safeguards as expected by NHS Digital such as a counter signature of someone with authority over the researcher who could enforce any action required if, for instance, there was a data breach. NHS Digital noted that their policy with regard to a counter signatory on honorary contracts had not changed. IGARD suggested that NHS Digital may wish to re-confirm the current policy position with their information governance directorate and then discuss further with the applicant.

3	Clinical Trials update Garry Coleman, Associate Director Data Access, updated members present on the 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 present welcomed the update.
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time, including the Associate Director Data Access, and closed the meeting.