Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 30th April 2020

In attendance (IGARD Members): Maria Clark, Kirsty Irvine (Chair), Imran Khan, Geoffrey Schrecker, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Garry Coleman (Items 3 and 4), Dave Cronin, Karen Myers, Tracy Taylor (Item 4), Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Paul Affleck, Nicola Fear.

1	**Declaration of interests:** Maria Clark noted a working relationship with an organisation involved with application NIC-233512-B7C4W (Northgate Public Services (UK) Limited), but noted no specific connections with the application and It was agreed this did not represent a substantive conflict of interest. Imran Khan noted a working relationship with some staff involved with application NIC-205466-T2F7N (University of York), but noted no specific connections with the application and it was agreed this did not represent a substantive conflict of interest. **Review of previous minutes and actions:** The outcomes of the 23rd April 2020 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting. The minutes of the 23rd April 2020 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data Applications**
2.1	<u>University of Aberdeen: MR756: Knee Arthroplasty Trial (KAT) (Presenter: Dave Cronin) NIC-322051-S8N9N</u> **Application:** This was an extension and renewal application for identifiable Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS); and an amendment to add the study sponsor, the University of Oxford as a joint Data Controller. The purpose is for a long-running trial, which started in 1998 to examine the clinical effectiveness and cost-effectiveness of four aspects of knee replacement surgery. In total, 116 surgeons in 32 UK centres participated in the trial. Between July 1999 and January 2003, 4070 potentially eligible participants were identified and 2352 gave consent and were randomised. The application was been previously considered on the 26th September 2019 when IGARD had recommended to approve for the University of Aberdeen to retain the data for a limited time period of 6 months, but not otherwise process the data by either the University of Aberdeen, or by any other organisation. IGARD supported NHS Digital that if this short-term extension DSA is not signed within 1 month, then a data destruction notice will be issued. **Discussion:** IGARD noted supporting document 1.0, version 8 of the Study Protocol provided a "confidentiality statement" and asked that a further explanation was provided for this statement. In addition, IGARD queried the reference in section 5(a) (Objective for Processing) to 'version 9' of a Study Protocol, and noting that they had only been provided with version 8,

	asked for confirmation if there was a version 9 of the Study Protocol and, if so, that a copy was provided for review. IGARD asked for more detail about the involvement of commercial organisation(s) and their activity in respect of this study and that written detailed confirmation was provided of any involvement. In addition, IGARD asked that further details were also provided of any funding or any other material benefits provided by or to these commercial organisations. IGARD asked that, pending the response to the queries raised on the commercial organisation(s) and the funding, that section 5 (Purpose / Methods / Outputs) and section 8 (Period and Funding) were updated with further details of the involvement of the commercial organisations and funding, as may be relevant and appropriate. IGARD noted that their predecessor the Data Access Advisory Group (DAAG) had previously endorsed in 2016 providing additional information to the cohort by way of a newsletters and queried how the study cohort had been communicated with since that date. IGARD noted DAAG's earlier request and asked that a suitable communication plan was produced with specific timeframes for communicating with participants. In addition, IGARD also asked that a special condition was inserted in section 6 (Special Conditions) stating that the applicant would produce a communication plan which outlined the distribution of an updated newsletter detailing the processing as set out in the application and any other developments in the study, for example, the involvement of the commercial organisations (if relevant). IGARD noted the dissemination to participants but queried how the results of this important study would be disseminated to the interested general public beyond the consented cohort and asked that this be given further consideration and details of such communication be provided. IGARD noted the list of publications in relation to the yielded benefits in section 5(d)(iii) and asked that this was updated to further to describe *how* the outputs had directly benefited *patients*. IGARD queried the reference in supporting document 3, Ethics Approval to an "amendment" and asked that further details of ethical approval amendment was provided as it was unclear. IGARD noted and endorsed NHS Digital's review that the University of Oxford 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 and that this application would not be suitable for NHS Digital's Precedent route. IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold, but not in any other way process, the data while work was undertaken to address the queries raised by IGARD. **Outcome Summary:** recommendation to approve subject to the following condition(s) 1. To provide written confirmation of the exact involvement of the commercial organisation(s) and their activity in respect of this study, and to provide details of any funding or any other material benefits provided by or to these commercial organisations. 2. To confirm if there is a version 9 of the study Protocol and if so, to provide a copy to IGARD. 3. If relevant, to update section 5 and section 8 with further details of the involvement of the commercial organisations and funding. 4. To produce a suitable communication plan with specific timeframes for communication with the participants of the cohort.

	The following amendments were requested: 1. To provide a further explanation of the confidentiality statement in version 8 of the study protocol provided as a supporting document. 2. To provide further details of the amendment to the ethical approval as referred to in SD3. 3. To provide details of how the results of the study will be disseminated to the interested general public beyond the consented cohort. 4. To insert a special condition in section 6 that the applicant will produce a communication plan which outlines the distribution of an updated newsletter detailing the processing as set out in the application and any other developments in the study, for example, the involvement of the commercial organisations (if relevant). 5. To update the yielded benefits to describe how outputs have directly benefited patients. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. 3. IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.2	<u>University of Aberdeen: PROSPECT: PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials (Presenter: Dave Cronin) NIC-324895-Y5W8Y</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) data for the purpose of a study which aims to investigate the treatment of women with pelvic organ prolapse. Prolapse is a progressive condition, often caused by childbirth, but symptoms appear many years later. Conservative management with pelvic floor exercises, oestrogens and pessaries might help in the earlier stages, however 10% of women will require surgery, which has a high failure rate with 3 out of 10 women requiring further surgery. Surgeons and researchers have suggested that mesh or graft reinforcement of the repair might provide a better chance of cure and prevent the need for further surgery. This is important because if the failure rate is reduced, women will be exposed to less risk and the costs may be less to the NHS. **Discussion:** IGARD welcomed the application and noted the importance of the study which was also a high profile study in the media. IGARD noted the reference in section 5(a) (Objective for Processing) to several organisations and other collaborators involved in a "wider project" and asked that further details were provided of the collaborators / organisations involved, the wider project and how it fitted in with the research outlined in this application. IGARD noted the information provided in supporting document (SD) 3.2, Ethics Approval that the Lead Collaborator was based at Manchester University and was also the Co-Chief Investigator for this study. In addition, IGARD also noted the role of the British Society of Urogynecologists outlined in SD 1.0, the Study Protocol. IGARD therefore asked that a further explanation was provided as to why the Lead Collaborator / Co-Chief Investigator at the University of Manchester and St Mary's Hospital Manchester and British Society of Urogynecologists were not considered joint Data Controller(s).

	IGARD queried why the importance of the study had not been highlighted within the application, particularly in light of the controversy and associated litigation action regarding the suitability of the treatments been studied, and asked that section 5 (Purpose / Methods / Outputs) was updated to highlight this, for example by referencing the NHS Choices website which considers vaginal mesh in pelvic organ prolapse surgery as a last resort. In addition, IGARD also suggested that section 5 was revised to specifically refer to the National Institute for Health and Care Excellence (NICE) guidelines which sets out a number of unanswered research questions for these types of surgeries, which IGARD felt this study could possibly usefully inform. There was a lengthy discussion with regard to the Patient and Public Involvement (PPI) in the study, and specifically noting the importance of this in light of the developments and publicity on the study subject, asked that further considerations were given to the current PPI and that to support the PPI going forward, a suitable PPI communication plan was produced, which included a specific timeframe for action. In addition, IGARD asked that consideration was given to the involvement of specific focussed interest groups, for example 'Sling the Mesh'. IGARD also queried if the PROSPECT Steering Committee (as referenced in the Study Protocol) composition had been recently reviewed and was active and asked that confirmation was provided, including giving special consideration to the patient and public involvement (PPI) at this level. IGARD noted that the cohort was going to be contacted via newsletter on an annual basis, however advised that they could not find any supporting evidence that there had been any recent communication, and asked that special condition was inserted in section 6 (Special Conditions) stating that researched would reinitiate their contact with the cohort to provide further information on the study specifically and on the topic generally. IGARD suggested that the applicant may wish to consider requesting additional NHS Digital data in the future to further support the study outputs. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide a further explanation why the Lead Collaborator / Co-Chief Investigator, University of Manchester and St Mary's Hospital Manchester and British Society of Urogynecologists are not considered joint Data Controller(s). 2. To revise section 5 to: a) Further highlight the importance of the study, particularly in light of the controversy and associated litigation action regarding the suitability of the treatments, for example by referencing the NHS Choices webpage which considers this surgery as a last resort. b) To refer to the NICE guidelines which sets out a number of unanswered research questions about these surgeries, in respect of which this study could usefully inform. 3. In respect of the PPI: a) To give further consideration to the current PPI, noting the importance of this in light of the developments and publicity on the study subject. b) To confirm if the PROSPECT Steering Committee composition has been recently reviewed and is active and consideration given to the benefit of PPI at this level. c) To produce a suitable PPI communication plan which includes a specific timeframe for action.

	d) To consider the involvement of specific focused interest groups, such as 'Sling the Mesh'. The following amendments were requested: 1. To provide details of the "wider project and "collaborators" and how it fits in with this research. 2. To insert a special condition in section 6 stating that researchers will reinitiate their contact with the cohort to provide further information on the study specifically and on the topic generally. The following advice was given: 1. IGARD suggested that the applicant may wish to consider requesting additional NHS Digital data in the future to further support the study outputs. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.3	<u>McKinsey & Company, Inc. United Kingdom: Standard Extract Subscription (Presenter: Dave Cronin) NIC-368233-L2N0W</u> **Application:** This was an extension and renewal application for pseudonymised Hospital Episode Statistics (HES) data; and an amendment to add Emergency Care Data Set (ECDS) to the Data Sharing Agreement. The purpose is to provide fact-based answers to NHS clients regarding identification, assessment and quantification of opportunities to improve the quality and efficiency of the NHS services that they deliver or are responsible for overseeing and regulating. NHS Digital advised IGARD that this application had been submitted following the submission of a briefing paper issued to IGARD on the 23rd April 2020 outlining the historical information of the application. NHS Digital confirmed that the applicant's Privacy Notice had now been published and that section 1 (Abstract) would need updating to reflect this. **Discussion:** IGARD noted the update from NHS Digital on the applicant's Privacy Notice having now been published and advised that this was difficult to locate other than via the URL link provided in the application, and asked that this was addressed and confirmation was provided that this was easily accessible to the wider public. In addition, IGARD queried the information in the Privacy Notice that stated national Opt Out's **do** apply, however section 3(c) (Patient Objections) stated that patient objections had **not** been applied; and asked that either the Privacy Notice or the application was updated to address this discrepancy. IGARD queried the benefits accrued to the commercial organisation and asked that section 5(e) (Is the Purpose of this Application in Anyway Commercial?) was updated in line with NHS Digital's Commercial Standard to include (but not limited to) how the benefits to the public were proportionately balanced against the commercial benefits accruing to the commercial organisation. IGARD noted the information in section 5(a) (Objective for Processing) that stated *"McKinsey will not use the NHS Digital data held under this agreement for any work carried out for any other organisation, including… Sustainability and Transformation Partnerships (STP)"* and queried the specific reference in section 5(c) (Specific Outputs Expected) to a specific STP that the NHS Digital data had supported; and asked that section 5(a) and 5(c) were revised to address this discrepancy. In addition, IGARD asked that a special condition was inserted in section 6

	(Special Conditions) for the Data Controller to provide to NHS Digital a process flow of the steps taken in terms of checking that any such data released to third parties complied with the terms of the Data Sharing Agreement (DSA). IGARD queried information outlined in section 5(c) that referred to 18 engagements that the applicant had used the NHS Digital data under this DSA for, and asked for clarification if the engagements were for separate projects or one project that had been separated into different activities, since this was not clear. IGARD queried the information in section 5(d) (Benefits) and noted that some of the dates for the benefits outlined had now passed and asked that this was updated to reflect the most recent and updated benefits and that any cost analyses outlined was both realistic and achievable. IGARD noted that the information provided throughout section 5 (Purpose / Methods / Outputs) was difficult to understand and asked that, to aid readability and comprehension this was updated to include (but not limited to) removing technical processing details from section 5(b) (Processing Activities) **Outcome Summary:** recommendation to approve subject to the following conditions: 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. The following amendments were requested: 1. To update section 5(e) in line with NHS Digital's Commercial Standard, to include (but not limited to) how the benefits to the public are proportionately balanced against the commercial benefits accruing to the commercial organisation. 2. To revise section 5(a) and section 5(c) to address the discrepancy when referencing projects with STP's and to insert a special condition in section 6 for the Data Controller to provide to NHS Digital a process flow of the steps taken in terms of checking that any such data released to third parties complies with the terms of the DSA. 3. To clarify if the 18 engagements outlined in section 5(c) are separate projects; or one project that has been separated into different activities. 4. To revise section 5(d) to reflect the most recent and updated benefits and that the cost analyses is realistic and achievable. 5. To aid readability and comprehension, to update section 5 throughout including (but not limited to) removing technical processing details from section 5(b). It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.4	<u>University of Cambridge: Long-term vascular complications in young people with childhood-onset type 1 diabetes (Presenter: Stuart Blake) NIC-316704-Z1Z7T</u> **Application:** This was a new application for pseudonymised National Diabetes Audit (NDA), identifiable Hospital Episode Statistics (HES) and Civil Registration data. The purpose is for a research project 'Long-term vascular complications in young people with childhood-onset type 1 diabetes'. Type 1 diabetes (T1D) is associated with an increased risk of developing long-term micro- and macro-vascular complications, affecting the kidneys, eyes and cardiovascular system. Risk of these complications is higher in people who develop T1D before the age of 16 years, compared to people who develop the disease during adult life. There is little data on the prevalence of these complications during adult life in people with an early diagnosis of T1D

	and limited knowledge as to which are the main risk factors during childhood and adolescence influencing the long-term risk for developing complications. NHS Digital advised that the application had reference to "identifiable" and that this was in the process of being amended to correctly state that the data was "pseudonymised". NHS Digital also advised that the Data Protection Act (DPA) Registration had expired on the 14th April 2020 and confirmed that the applicant had submitted their renewal on the 25th March 2020, however this had not been acknowledged or processed due to backlogs within the system. **Discussion:** IGARD welcomed the application and noted the valuable research and study, in addition IGARD also praised the Patient and Public Involvement (PPI) as outlined in the application. IGARD noted the update from NHS Digital and supported the amendment to the application to replace the reference from "identifiable" to "pseudonymised". IGARD also noted the update from NHS Digital on the applicant's DPA Registration and asked that a special condition was inserted in section 6 (Special conditions) that the DPA Registration has been updated. IGARD noted that section 5(b) (Processing Activities) referred to an anonymous dataset, however some of the supporting document's (SD), for example SD 2.2, the Health Research Authority Confidentiality Advisory Group (HRA CAG) form stated that identifiers would be kept for analysis; and asked that the processing description in section 5(b) was aligned with the supporting documents. A number acronyms were noted within section 5, for example "JDRF", 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. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that on renewal with Health Research Authority Confidentiality Advisory Group (HRA CAG), the applicant may wish to consider requesting that opt out's do not apply given the cohort consented to take part in the study. IGARD suggested that the applicant may wish to consider requesting additional NHS Digital datasets, years of data, or an ongoing refresh of the data, to further support the study outputs. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To update section 5(b) to align the description of the processing with the description provided in the supporting documents, for example SD 2.2 and the HRA CAG support. 2. To amend section 5 to ensure that all acronyms upon first use in section 5 be defined and further explained, as may be necessary for a lay reader (for example *"JDRF"*). 3. To insert a special condition in section 6 that the DPA Registration has been updated. The following advice was given: 1. IGARD suggested that on renewal with CAG the applicant may consider requesting that opt outs do not apply given the cohort consented to take part in the study. 2. IGARD suggested that the applicant may wish to consider requesting additional NHS Digital datasets, years of data, or an ongoing refresh of the data, to further support the study outputs.

2.5	Northgate Public Services (UK) Limited: Neurosurgical National Audit Programme (NNAP) (Presenter: Kimberley Watson) NIC-233512-B7C4W **Application:** This was an amendment application to 1) Two further fields DOMPROCCODE (which is the Trust derived dominant procedure) and LOPATID (which is local patient identifier) have been added to the HES Admitted Patient Care Product; 2) an addition of accessing the data on a laptop by the Consultant neurosurgeon; 3) to remove Sungard as a Data Processors and storage location; 4) a request to resupply NHS Digital data. Neurological National Audit Programme (NNAP) was established by the Society of British Neurological Surgeons (SBNS) in 2013 as part of a major quality improvement initiative which aims to support neurological units in the UK to improve patient care, outcomes, safety and experiences by providing high quality, robust audit data this is analysed and presented in consistency and clinically relevant way. **Discussion:** IGARD queried if NHS Digital had assessed the LOPATID in the context that it would be provided alongside mortality data and were advised by NHS Digital that it had been assessed and that the data was not considered to be identifying data. IGARD queried the role of the auditing neurosurgeon who would be accessing the pseudonymised data on a laptop during visits to NHS Trusts, and asked that further details were provided on their role and responsibility; including further justification of the how they would be using the additional copy of NHS Digital data held on the laptop whilst carrying out their role on remote sites, since albeit low, it was still a potential security risk. IGARD noted specific reference to a named individual and a specific named technology device within the application and asked that this was reviewed to ensure that these references were amended to be a role description and that reference was made generally to technology devices, otherwise any change to the specific individual or name technology would be a breach of the Data Sharing Agreement (DSA). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **ACTION:** IGARD asked that the advice that has come to IGARD to date in relation to the criteria for potential identifiers becoming identifiable was summarised and to agree the position, for example when data of death is applied and why this was not considered identifiable data. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To provide further details of the role and responsibility of the auditing neurosurgeon and justification of how they will be using the duplicate set of NHS Digital data held on the laptop in carrying out that role on remote sites. The following amendments were requested: 1. To review the application throughout to ensure that where there is reference to a specifically named individual and named technology devices that this is amended to be a role description and to refer more generally to technology devices. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
2.6	University of York: Modelling Healthcare-Evidence Responsive Behaviours (HERBs) in Doctors: A proof of concept study (Presenter: Kimberley Watson) NIC-205466-T2F7N **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) data for the University of York and the General Medical Council (GMC). The aim of the study is to model how responsive different graduate groups of consultants are to the

	publication of new guidelines regarding the use of drug-eluting stents in percutaneous coronary intervention (PCI). Stents are small mesh tubes inserted to keep arteries open after a procedure called angioplasty (percutaneous coronary intervention, or PCI). Drug-eluting stents have a polymer coating over mesh that emits a drug over time to help keep the blockage from coming back. The application was been previously considered on the 23rd January 2020 when IGARD had deferred pending: To update section 1 and section 5 to reflect Article 6 and 9 of GDPR for both the GMC and the University of York (i.e. the GMC requires an Article 6 legal basis and the University of York requires a single Article 9 legal basis); to update section 5 to clearly state that the University of York is processing but **not** holding the data; to clearly outline the focus of the study in section 5 and to clarify why the specific stenting procedure outlined has been selected; to update the application throughout to ensure that any reference to *"guidelines"* is amended to clearly reflect that these are *"NICE guidelines"*; to provide a further explanation clarifying why only *"consultants"* have been selected for this study; to reconsider the statement in section 5(a) that states *"…the potential impact on doctors is very low"*; to provide further explicit details within section 5(b) of the data is being linked, particularly referencing the protocol that provides further details of training, gender and ethnicity; to update section 5(d) clarifying how this study will benefit the health and social care system; to acknowledge and address the ethical issues raised by this study; IGARD suggested the applicant may wish to consider involving the BMA or other relevant doctor stakeholder group(s). **Discussion:** IGARD noted that the application had been updated to reflect some of the comments previously made. IGARD noted that at the last review of this application on the 23rd January 2020, it was discussed and agreed that there were a number of ethical issues that may arise from this study and IGARD had asked that these were acknowledged and addressed within the application. However, having reviewed the responses, in IGARD's view the outstanding issues in relation to the actual and potential ethical issues raised by this study had not fully and comprehensively been addressed. IGARD noted that although Ethics approval was not required because the request did not include the flow of identifiable data, suggested that the applicant proactively seek ethics approval from the University of York for this study, since they may also have wider ethical questions to address. IGARD also suggested that as per the previous advice, that the applicant may wish to consider directly involving the British Medical Association (BMA), General Medical Council (GMC) or other relevant doctor stakeholder group(s) and to proactively seek a positive endorsement for the study, for example from the Black, Asian and Minority Ethnic (BAME) Doctors Forum at the GMC. IGARD queried the procedure and guidelines selected as a model and advised that these present numerous issues, which as a result means the study was not as straight forward as initially presented, including the fact that you could not hold someone to account for not adopting guidelines. IGARD queried the quality of the data being studied and advised that there were a number of confounding factors that may have an impact on the quality of the study outputs. IGARD noted the 2018 UK Medical Education Database (UKMED) minutes that had been provided via a link in the application and supporting materials, and confirmed that they supported and endorsed the suggestions outlined; and queried if any of the suggested

	actions had taken place, for example (but not limited to) the clear and transparent communications plan. IGARD queried how the outputs of the study would be communicated and suggested that careful consideration of this was given and that on this rare occasion, IGARD cautioned that in view of the potentially sensitive nature of the outputs their dissemination might be limited to specific organisation(s) and in the current climate, due to this potential sensitivity any findings may need to reviewed and plans put in place by the GMC, for example. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** Unable to recommend for approval 1. Outstanding issues in relation to the actual and potential ethical issues raised by this study have not fully and comprehensively been addressed. 2. IGARD suggested that although it may not be a requirement, that the applicant proactively seeks ethics approval from the University of York for this study. 3. The procedure and guidelines selected as a model present numerous issues, which as a result means the study is not as straight forward as initially presented. 4. Due to the quality of the data being studied, there are a numerous confounding factors that may impact on the quality of the study outputs. 5. IGARD supported and endorsed the suggestions outlined in the 2018 UKMED minutes provided as a link in the supporting materials and queried whether the suggested actions have taken place, for example (but not limited to) the clear and transparent communications plan. 6. IGARD suggested that careful consideration was given to how the outputs were communicated and advised that on this rare occasion they cautioned the restriction of the outputs limited to specific organisation(s). 7. IGARD suggested as per previous advice that the applicant may wish to consider directly involving the BMA, GMC or other relevant doctor stakeholder group(s) and proactively seek a positive endorsement for the study, for example from the BAME Doctors Forum at the GMC.
3	<u>Trusted Research Environment (TRE) (Presenter: Garry Coleman)</u> NHS Digital provided an overview on a paper that has been developed by NHS Digital, Health Data Research UK, National Institute for Cardiovascular Outcomes Research (NICOR) and the British Heart Foundation (BHF). The paper proposes a legally compliant approach to link data and provide access to secure analytical environments for researchers to answer rapid COVID-19 related research questions, across the four nations, using cardiovascular disease as an exemplar. It will be subject to review after the COVID-19 emergency, or after six months, whichever comes first. IGARD welcomed and thanked NHS Digital for the overview of the publicly available paper.
4	<u>Migration of MRIS Products (Presenters: Garry Coleman / Tracy Taylor)</u> The briefing paper was to inform IGARD about the new automated cohort management and extract service which will replace the Medical Research Information Service (MRIS) following it's decommissioning on 1st June 2020. This change has significant implications for existing service users, and means that applications for cohorts will be presented differently to IGARD.

	Throughout April / May 2020 each organisation that has an active Data Sharing Agreement (DSA) in place and is expecting dissemination(s) of MRIS products via the DSA, will be migrated to the new service using DARS Online. There are three main areas for IGARD to note: 1) IGARD will see different products being listed on new applications for cohort tracking services; 2) Precedents will continue to be applied where the products are being swapped over (i.e. no increase in data fields being provided, but being presented differently); 3) Applications previously reviewed by IGARD will return at a later date listing new products. IGARD welcomed and thanked NHS Digital for the comprehensive briefing paper and looked forward to receiving the briefing paper as a supporting document with an application at a future meeting. IGARD suggested that when applications were approved via NHS Digital's precedent route, it would be helpful if section 1 (Abstract) could refer to the migration from MRIS to the new standard extractions.
5	Returning Applications 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-204580-F5B0C The Clatterbridge Cancer Centre NHS Foundation Trust • NIC-25945-T8Q0Z University of Cambridge 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 which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis. Moving forward, IGARD agreed that Covid-19 and COPI regulation 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.
6	Covid-19 update To support NHS Digital's response to Covid-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss Covid-19 and COPI regulation urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meeting's, 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 28th April 2020 can be found attached to these minutes as Appendix B. IGARD noted that there were no additional Covd-19 related items to discuss at this week's meeting.
7 **7.1**	AOB: NIC-91972-S9W9T - 3M United Kingdom PLC IGARD noted that the application had returned to IGARD due to the fact that the condition previously advised when presented to IGARD on the 9th April had not been met: *3M United Kingdom PLC to provide confirmation that they have not launched the commercial Tool*.

	IGARD suggested that the applicant provide an explanation within the application that they are revalidating the live tool and to update their privacy notice to reflect this revalidation and that the updated application be presented back to IGARD out of committee, as per due process. 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.

Annex A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 24/04/20

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-351761-F8Z6V	Northgate Public Services (UK) Ltd	12/03/2020	1. In relation to the cohort numbers: a) To provide clarity of the cohort numbers within section 1. b) To set out in section 1 that the cohort relates to *"cohort 2"* from NIC-58668. c) To clarify who is in the cohort and the dates from which they were consented from. d) To confirm the cohort within the table in section 3(b). 2. To clarify what *"Beyond Compliance"* is, for example an advisory group, a service etc; and to provide a consistent narrative throughout the application.	IGARD Members	OOC by quorum of IGARD members	Condition 1: To move the critical information from SD11 into the beginning of section1 and move the most historic information into the supporting document (and clearly flag in section1 that there is further historic information in SD11). As follows: 1. In relation to the cohort numbers: • To provide clarity of the cohort numbers within section 1. *To move the explanation from SD11 to Section1.* • To expand the reference no to read **NIC** – *58668.* • To clarify who is in the cohort and the dates from which they were consented from. *To replicate in section 1.*

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

Annex B

Independent Group Advising on the Release of Data (IGARD)

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

28th April 2020, held via video conference

In attendance (IGARD Members): Paul Affleck, Kirsty Irvine (Chair), Geoffrey Schrecker.

In attendance (NHS Digital): Vicky Byrnes-Watts, Liz Gaffney, Frances Hancox, Karen Myers (Observing), Vicki Williams.

2	**Meeting Remit** This weekly meeting is convened to support NHS Digital's response to the COVID-19 situation and is separate from the IGARD BAU meetings. IGARD members present will only be making comments and observations on any items that were presented, and will not make 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 will 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-156334 University of Cambridge: INTERVAL and COMPARE trial cohorts: long term follow up of health outcomes and associations with genetic, biological and lifestyle traits **Background**: This was a verbal update to the urgent amendment request that had been presented to the COVID-19 Response meeting on the 21st April 2020, in order support research relating to the COVID-19 pandemic. NHS Digital noted that they had discussed with the applicant and addressed the points previously raised including inserting a number of special conditions to address the ethics

	approval before any data linkage, communications to have taken place before any data linkage and reviewing the COVID-19 element before the 30 September 2020. **IGARD Observations** IGARD members welcomed the verbal update from NHS Digital and endorsed a number of key amendments to the application including: • Inserting a special condition in section 6 that ethics approval should be in place before any data linkage takes place • Inserting a special condition in section 6 that the COVID-19 related element of the application is reviewed on or before the 30 September 2020 in line with the current emergency legislation in place • Inserting a special condition in section 6 that the applicant must have provided both the COMPARE and INTERVAL cohorts with updated transparency materials including any proposed data linkages and that this must align with the updated ethics approval. In addition, that the COMPARE cohort, as per the consent materials, must be provided with the ability to opt out of this particular study and suggested that it be sufficiently granular that the cohort may opt out of the linkage for this study but continue to be opted in to other parts of the study. NHS Digital noted that the applicant's DPA registration had been submitted to the ICO a month ago however the renewal details had still not been updated to the ICO website. IGARD were in agreement with NHS Digital's proposed way forward that evidence of renewal submission be provided would suffice but including a special condition section 6 that the applicant must notify NHS Digital immediately if the registration lapsed for any reason. IGARD members advised they would wish to review this application again when it comes up for renewal, amendment or extension. IGARD members suggested this application would not be suitable for NHS Digital's precedent route.

	ACTION: separate to this application, it was agreed that the practicalities of uplifting, terminating or extending COVID-19 data flows be added to a future COVID-19 Response meeting
2.2	<u>NIC-373132 The Nuffield Department of Primary Health Services, University of Oxford: R15 the Platform Randomised trial of INterventions against COVID-19 in older peopLE (PRINCIPLE) Trial</u> **Background:** NHS Digital noted this was a clinical trial from University of Oxford which aims to evaluate potential treatments as they are identified and to test these potential treatments as they become available. The aim of the study is to find out whether selected treatments given to those at higher risk of becoming more ill when they are infected with COVID-19 helps reduce the need to hospitalisation and the length of stay required and helps people to recover quicker with fewer complications. The clinical trials aims to recruit at least 3000 people. NHS Digital noted that an application was not available for review but had provided a copy of the consent form, patient information sheet (PIS) and protocol. **IGARD Observations:** IGARD members noted and endorsed the comprehensive review undertaken by NHS Digital of the materials provided. NHS Digital noted that the study had already started to recruit from the 17 April 2020 and that this was included on their website, however IGARD noted that NHS Digital had not been referred to in the consent form (and observed that any reference to a "regulatory body" related to the oversight of clinical trials and did not encompass NHS Digital). IGARD members suggested that since the term '*identifiable*' may also include pseudonymised data, that the applicant may wish to use the term '*identifying*' or the phrase '*will not directly identify you*'. IGARD members queried the necessity of using a US-based Data Processor, but without any further information set out in the application or supporting documents, suggested the applicant

	would need to consider the handling of personal data under GDPR and complying with any other additional requirements when sending data abroad. IGARD members queried the follow up period and clinical trial end date as outlined in the supporting documents. Since the trial would want to know cause of death and mortality the applicant may wish to reconsider the end date outlined in the documentation provided and the short follow up period of 6 months after the trial ends. IGARD members noted that the trial had started on the 17 April and that the cohort consented had been given consent on a form that did not reference NHS Digital, any data linkage nor the fact that identifiers were being sent. Although it was noted that NHS Digital had been referenced in the PIS, it would be best practice for more detail about the linkage and data sharing to be expressly noted in the consent form. IGARD members noted that the applicant had spoken with their ethics committee but that a further detailed review was still to be provided by the ethics committee and that the consent materials should be amended to align with any feedback received. In terms of the cohort members already consented, since this is a current active trial, the most expedient way of updating may be via the clinical trial's portal and providing updated consent materials online with functionality for the applicant to have to actively read and agree with the more detailed description of the processing (as approved by the revised ethics support and express consent aligned with the processing involving NHS Digital). NHS Digital noted that the PIS noted access to medical records from Public Health England, NHS Digital and other bodies and whether this was sufficiently clear that the applicant was linking these datasets. IGARD members noted that the cohort may not think they were consenting to one large dataset but that these documents should clearly align with the ethics review. **ACTION:** separate to this application, IGARD suggested it work with NHS Digital and the Health Research Authority (HRA) to develop rubric wording on the HRA clinical trials website which, inter alia, encompassed data linkage to NHS Digital data.

2.3	NIC-374190 Genomics England: COVID-19 specific work **Background:** The GenOMICC (Genetics of Susceptibility and 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. Genomics England are hoping to identify these genes to help use existing treatments better and to design new treatments to help people survive critical illness. To do this, Genomics England will compare DNA and cells from carefully selected patients with samples from healthy people. NHS Digital noted that the applicant was currently going through ethics approval, using the similar consent materials provided for the 100,000 Genomes Study and would be looking to recruit 20,000 to the study. **IGARD Observations:** IGARD members noted the importance and value of the study but queried if the study could produce genomic-related outputs within a few weeks to support intensive care management or assist in the management of the current pandemic. Justification is necessary for why this study requires real-time data under urgency. In addition, for this and any other application presented at these meetings, that IGARD members are unable to comprehensively assess the consent materials without detailed processing information and that any comments on the consent materials are made with this caveat. IGARD members noted a number of Data Processors and complex data flows and suggested that a data flow diagram be provided that outlined each flow, each legal basis and each Data Controller / Data Processor for each flow of data. IGARD members noted that the consent materials provided as SDs, v1.08 and v2.0, were not clear as to which participants had been consented on which forms, since the website clearly stated they had been recruiting to the study since 2016 and that a clear consent history should be provided within the application. In addition, since the consent materials were silent on data linkages and flowing of identifiable data to NHS Digital, that in order to meet NHS Digital's

	Duty of Confidentiality Standard that as soon as reasonably possible, and before any data linkage takes place, that the cohort is sent up to date transparency materials explaining all changes. IGARD members noted reference to 'lifetime and beyond' within the consent materials provided which indicated following the cohort's mortality-related data and that the data would be used after their death: but in a way that was patient-friendly. As a separate point, IGARD agreed to discuss at a future meeting if this form of wording was a useful and informative way of indicating that mortality and cause of death data would be collected and used long term, without resorting to less precise euphemisms such as "vital status". IGARD members noted reference to sponsor / sponsors / co-sponsors in various SD's (including SD3.2) provided and suggested that clarity be sought as to who and how many sponsors were involved, since there was a discrepancy in the language used. IGARD members noted within the PIS that there was reference to de-identified information and asked for clarify as to whether identifying data was flowing into NHS Digital and if confirmed that granularity should be included in the consent forms allowing for the flow of identifying data to NHS Digital. In addition, IGARD members noted in SD3.2 PIS that imaging data was being requested and that images could not be de-identified since they would automatically be stamped with patient names and NHS numbers and that NHS Digital should clarify that this is diagnostic data, not a copy of the relevant patient images.
2.4	<u>NIC-365354-R3M0Q University of Oxford: R1 (D09) Data support to COVID-19 RCT</u> **Background:** This was an amendment application that had previously been approved by NHS Digital's SIRO on 31 March 2020 for access to data for the Randomised Evaluation of COVID-19 thERapY (RECOVERY). The study aims to compare several different treatments that may be useful for patients with COVID-19 and the new trial was classed as an 'Urgent Public Health Research Study'. The amendments to the previous DSA were to include a new study protocol and new consent materials; relevant ethical approval support; supporting letter from the Chief Medical Officer encouraging national take up of the trial; removing charges for the update of the agreement;

	adding additional HES APC field; amending the mortality data disseminated; including clarification of using the NHS number, study ID and DOB to facilitate data linkage; and insertion of an additional special condition. NHS Digital note that this was a rolling DSA. I**GARD Observations:** IGARD members noted that they had previously provided initial comments on the consent materials to NHS Digital in March 2020 without prejudice to any further comments that would arise in the context of a live application. IGARD members were pleased to note the inclusion of an assent form, which they had previously advised would be best practice to produce. IGARD members noted that applicant was updating their privacy notice but that no timescale had been included as to when that would be available and since there was considerable information on the trial website and NHS Digital suggested that applicant should be able to provide a GDPR compliant privacy notice within six weeks. IGARD members agreed with this approach and suggested that the privacy notice also be updated to be clear about the retention period for the data since a reader needs to know the intended study end definition given in the protocol to understand what the notice currently states. IGARD members noted that since this was a rolling DSA and the yielded benefits were accruing quickly from the outputs that section 5(d) should be updated at each iteration thereby demonstrating that rapid release of and processing of data may yield rapid benefits and outputs.
2.5	<u>CCG NHS Shielded Patient List</u> NHS Digital gave a brief update to IGARD members with regard to the Shielded Patient List and the transfer of this list to CCG's, via the DSCROs. IGARD members asked if a copy of the letter from the Executive Director Information Governance was available to IGARD in order to inform any next steps, including any follow up questions that IGARD Members may have as a result of the list being provided to CCG's.

	Subsequent to the meeting: NHS Digital provided the link to the published letter: https://digital.nhs.uk/coronavirus/shielded-patient-list/guidance-for-other-organisations
3	Publishing an Open Data Set for the Shielded Patient List (SPL) NHS Digital has asked for IGARD advice with regard to a number of questions raised by the Parliamentary Under-Secretary of State for Health and the publishing of an anonymous open data sets for SPL to support both planning and public debate. IGARD members noted that if the data was truly anonymised then it was in the public interest to make this data publicly available and were strongly supportive of NHS Digital's approach to publishing the open data set for SPL. IGARD provided written comments outside of the meeting.
4	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.