Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 13 May 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member (Item 6 only)
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member (Items: 1, 2.1 – 2.6, 4, 5, 7.1)
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Michael Chapman	Director of Research and Clinical Trials (Item 6 only)
Dave Cronin	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Arjun Dhillon	Data Access Request Service (DARS) (Item 6 only)
Louise Dunn	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS) (Item 3 only)
James Gray	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS)
Joanna Warwick	Data Access Request Service (DARS) (Item 3 only)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. Nicola Fear noted a personal and professional link to the Lead Investigator and lead organisation (University of Oxford) [for NIC-324368-Q0H5T], however confirmed that no discussions had taken place with the staff involved about the application, and it was agreed this was not a conflict of interest. Dr. Maurice Smith noted that in his role as a Liverpool CCG Governing Body Board member and CCIO he has a connection to Liverpool University which carries out a variety of data analysis for Liverpool CCG. In his role as a GP partner at Mather Avenue Surgery, Liverpool he has a direct financial interest in the Liverpool Quality Improvement Scheme [NIC-16656-D9B5T] as his practice receives payments by virtue of taking part in that scheme. It was agreed this did not preclude Dr. Smith from taking part in the discussions about this application, however it was agreed that he would not participate in making a recommendation about the application. **Review of previous minutes and actions:** The minutes of the 6th May 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	<u>University of Liverpool: HES Extract – Place Based Longitudinal Research Resource-Developing neighbourhood resilience, reducing health inequalities (Presenter: Frances Hancox) NIC-16656-D9B5T-v4.2</u> **Application:** This was an amendment application to 1) request a one-off dissemination of the latest available Hospital Episode Statistics (HES) Admitted Patient Care (APC) and HES Accident and Emergency (A&E) data, and 2) to change the processing and storage location due to a server move. The purpose of the additional data is to address the current priority of ensuring effective control and service redesign measures during the COVID-19 pandemic. This will be used to evaluate specific area-based control measures including the introduction of the Mass Testing pilot in Liverpool. The overall purpose is for research to advance the University of Liverpool's understanding of the causes of poor health and evaluate the effectiveness of interventions and policies in order to effectively promote public health. **Discussion:** IGARD noted and thanked NHS Digital for the additional tracked change document that was provided for review; which made it clear and transparent as to what changes had been made to the application following the last review by the IGARD's predecessor, the Data Access Advisory Group (DAAG) in 2016. IGARD noted within section 1 (Abstract), that following the last independent review by DAAG in 2016, version 3.0 of the application had been approved via NHS Digital's Precedent route in 2019, and that the Data Sharing Agreement (DSA) had been extended to 2022. IGARD

	queried if NHS Digital's Data Production Team were content that the fullest possible data minimisation has been applied, in light of the additional years of data that have been added to the DSA and noting NHS Digital's DARS Standard for Data Minimisation, and asked that section 1 was updated with confirmation that Data Production were content. IGARD noted that section 3 (Datasets Held / Requested) stated that the mental health data (HES APC), would be minimised to general episodes, for example, those formally detained under *"mental health"*; and noting that it was not clear what was meant by this. IGARD asked that section 3 and section 5 (Purpose / Methods / Outputs) were updated to clarify that the mental health data had been minimised to only remove those detained under the Mental Health Act 1983. IGARD noted that a number of the outputs outlined within the application were specifically related to mental health, and suggested that the applicant may wish to apply for the Mental Health Minimum Data Set (MHMDS), since the data requested under this application may not include the mental health conditions that may be a contributing factor to increased health care usage. IGARD would be supportive of the flow of the MHMDS should the applicant wish to apply for it. If the MHMDS was added to the application, IGARD advised that they would not need to re-review the application, but would ask that an appropriate justification for this additional data be added to section 5 for transparency. IGARD queried the outputs and benefits in section 5(c) and section 5(d), noting that some of these were historical, and that it was not clear how (or if) they had been realised. NHS Digital advised IGARD that the applicant had confirmed that a number of the reports that were referred to in section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) had either been published, or were in the process of being published, and that the application would need updating to reflect the latest information. IGARD noted and thanked NHS Digital for the verbal update, and supported the update to section 5 in respect of the outputs and benefits. IGARD noted a number of acronyms in section 5, and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. IGARD also noted the reference to *"Lower Super Output Area"* in section 5, and asked that this was updated to provide a further supportive explanation. In addition, IGARD queried the reference to *"…higher geographies and by GP practice…"* in section 5, and asked that this was updated with a further supportive explanation. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* **Outcome:** recommendation to approve subject to the following condition: 1. NHS Digital to provide confirmation in the application abstract that NHS Digital's Data Production Team are content that the fullest possible data minimisation has been applied (particularly in light of the additional years of data that have been added to the DSA via the Precedent route since it was last independently reviewed in 2016). The following amendments were requested: 1. To amend section 5 with the relevant updates, as outlined verbally by NHS Digital, in respect of the outputs and benefits. 2. To update section 3 and section 5, to clarify that the mental health data has been minimised to only remove detention under the Mental Health Act. 3. In respect of the language used within section 5:

	a) To amend section 5 to ensure that all acronyms upon first use are defined and further explained if the meaning is not self-evident. b) To update the reference to *"Lower Super Output Area"* in section 5 with a further supportive explanation. c) To update the reference to "…higher geographies and by GP practice…" with a further supportive explanation. 4. To update section 5(d) to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". The following advice was given: 1. IGARD noted that a number of the outputs outlined within the application were specifically related to mental health, and suggested that the applicant may wish to apply for the Mental Health Minimum Data Set (MHMDS). IGARD would be supportive of this flow of data should the applicant wish to apply for it. If this dataset was added to the application, IGARD would not need to re-review but would ask that an appropriate justification for this additional data should be added in section 5 for transparency. It was agreed the conditions would be approved out of committee (OOC) by the IGARD Chair.
2.2	Keele University: REadmissions, Adverse Complications and ouTcomes following Acute Myocardial Infarction Study (REACT-AMI) (Presenter: Catherine Day) NIC-306651-W7L4C-v0.18 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) data and Hospital Episode Statistics (HES) Admitted Patient Care data; for the purpose of a study, which will assess the incidence of immediate and post-discharge complications in a cohort of patients admitted with a diagnosis of acute myocardial infarction (AMI) in the last 15 years. The prevalence and nature of subsequent cardiac and non-cardiac events such as readmission with further AMI, strokes, or other medical conditions will also be examined. This study aims to identify the future risk of complications, determine which complications are associated with increased risk of dying or future AMI, and identify the risk factors associated with such complications. It is hoped that using these risk factors and new risk scores could also be developed to predict future events and risk stratify patients presenting with AMI; which is relevant for all doctors managing these patients as it will allow tailoring of treatment according to the patient baseline risk and risk of future cardiac and non-cardiac events. This study will be a retrospective cohort study of all adult patients aged over 18 years in the Myocardial Ischaemia National Audit Project (MINAP) registry, admitted with a diagnosis of AMI between 1st January 2005 and 31st March 2020. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted that section 3(b) (Additional Data Access Requested) stated that the legal basis for the dissemination of the NHS Digital was s251 of the NHS Act 2006, however, noting that the data was pseudonymised, asked that section 3(b) was updated to remove this reference, and instead note the relevant legal basis for the dissemination of pseudonymised data, as per usual process. IGARD noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support, expressly stated that support was not given to flow the postcode data; and noting that this had not been acknowledged within the application. IGARD asked that section 1 (Abstract) was updated to reflect that the postcode data was not flowing under this application.

	In addition, that section 1 was updated with confirmation that NHS Digital had assessed the datasets, and were content that no postcode data would flow. IGARD noted that supporting document 3.1, the HRA CAG letter of support, confirming contentment with the opt-out arrangements. IGARD advised that it was essential that the applicant uploaded the patient information leaflet (PIL) to The National Institute for Cardiovascular Outcomes Research (NICOR) website, as a matter of urgency, and well before the data flowed from NHS Digital in order to give participants ample opportunity to opt-out. The applicant should also make it clear *how* a cohort member could opt-out. IGARD noted the HRA CAG specific conditions of support outlined in supporting document 3.1, and asked that a special condition was inserted in section 6 (Special Conditions), that the applicant must ensure the HRA CAG specific conditions of support were met during the life of the DSA. IGARD noted the comparison to the healthcare model in the United States of America in section 5(d) (Benefits), and asked that this was removed, as it was not a suitable direct comparator since the health care systems are completely different. IGARD queried the benefits outlined in section 5(d), for example, the *"…significant cost savings to the NHS…"*, and asked that this was updated with more specificity, to expand on the benefits accruing directly to the public / patient experience, and other general benefits, for example, the wider societal savings and hospital productivity. IGARD suggested that section 5 (Purpose / Methods / Outputs) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) such as *"index hospitalisation"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use. IGARD noted the references within section 5 of the application to *"managing"* patients and asked that this was amended, for example to *"providing care to patients"*. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3(b) to remove reference to s251 being the legal basis for the dissemination of data by NHS Digital. 2. In respect of the postcode data: a) To update section 1 to state that HRA CAG has expressly **not** given support to flow the postcode data. b) To update section 1 to confirm that NHS Digital have assessed the datasets, and are content that no postcode data will flow. 3. To insert a special condition in section 6 that the applicant must ensure the HRA CAG specific conditions of support are met during the life of the agreement. 4. The applicant to ensure that the PIL is uploaded to the NICOR website as a matter of urgency, and well before the data flows, to give participants ample opportunity to opt-out; and to make it explicitly clear how a cohort member can opt-out; and in line with the HRA CAG support. 5. To update section 5 to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*".

	6. To amend section 5 to ensure technical terms such as *"index hospitalisation"* are explained. 7. To update section 5 to ensure any references to "*managing*" patients is amended, for example to *"providing care to patients"*. 8. In respect of the benefits in section 5(d): a) To amend or remove the comparison to the US healthcare model as this is not a suitable comparator. b) To update section 5(d) to expand on the benefits accruing directly to the public / patient experience and other general benefits such as wider societal savings and hospital productivity.
2.3	University of Oxford: Cerebral Palsy in the British Orthopaedic Surgery Surveillance Study (CPinBOSS Study) (Presenter: Vicky Byrne-Watts) NIC-324368-Q0H5T-v0.15 **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data; for the purpose of a study, aiming to identifying the total number of patients with cerebral palsy, that are eligible for Single Event Multi Level Surgery (SEMLS), for example, the incidence of children with cerebral palsy who fulfil the criteria for this type of surgery; and to look at the variation in the surgeons' criteria in selecting children for surgery by analysing the children's clinical characteristics. SEMLS is a surgical intervention that involves a minimum of two surgical procedures (bony or soft tissue) undertaken at a minimum of two different levels (e.g. hip and knee or thigh and calf) with the objective to improve walking function within cerebral palsy patients. There are major differences between the Trusts that perform SEMLS in terms of patient selection and the choice of the specific surgical interventions. The application was been previously considered on the 4th February 2021, when IGARD had deferred pending: 1) In respect of the data requested: a) To provide justification of why national data is required, for example, could this this be filtered by participating NHS Trust; b) to clarify why the extensive range data fields, for example ethnicity data, is required; c) to provide further confirmation of how the data fields listed in section 5(b) are being utilised for non-identifying case ascertainment. 2) In respect of the case ascertainment statement in section 5: a) to update the apparently inconsistent narrative in section 5 that refers to live data links, and the ability to spot duplications; b) to update section 5 to provide a clear explanation of how case ascertainment, purely on case number counts, is compatible with the narrative, which may suggest there may be re-identification activity by lead surgeon or others; c) if this is case ascertainment purely on numbers to explain how this process is practical and manageable for the NHS Trusts receiving the data. 3) To update section 5(d) to expand the information provided that infers there is a larger study, and to provide an explanation of how this study fits in with any larger study. 4) To clarify if there are any additional storage locations and to amend section 2(b) if appropriate. 5) The following advice was given: IGARD suggested that, noting that much of the language within the public facing content of the application has been carried over from a scientific protocol, that a careful review was undertaken of the language used, for example, changing the reference from *"…how patients with Cerebral Palsy are surgically managed..."*, to refer to the *"condition"* being managed. 6) Separate to this application, IGARD suggested NHS Digital may wish to raise with the applicant the wider issue of what the legal basis is for the broader activity referred to within the applicant, particularly patient details collected on the database and how they do this, and then follow that patient, without consent; and to upload any evidence on to CRM. 7) IGARD suggested that this

	application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. In respect of deferral point 3, *"To update section 5(d) to expand the information provided that infers there is a larger study, and to provide an explanation of how this study fits in with any larger study"*, IGARD noted that this had been addressed within the updated application, however asked that for complete transparency, section 1 and section 5 were updated with express confirmation that personal data would **not** be shared with the Trusts in order to carry out the processing. In addition, in response to deferral point 3, IGARD noted that within the service evaluation there was a *"nested consented cohort"* and asked that section 5 was updated with a brief explanation of how patients may be recruited to the nested consented cohort, as this was not clear. IGARD advised that they had previously suggested that a careful review was undertaken of the language used within the application, for example, changing the reference from *"…how patients with Cerebral Palsy are surgically managed..."*, to refer to the *"condition"* being managed; and noting that this had not been addressed in the latest version of the application, asked that section 5 was updated accordingly. IGARD noted the reference in section 5(a) to the UK General Data Protection Regulation (GDPR) Article 6(1)(e) legal basis being for the *"Lawfulness of Processing"* and asked that it was updated to correctly reflect that Article 6(1)(e) was for public task. IGARD noted a number of acronyms and technical terms in section 5, for example, *"Delphi consensus"* and *"CPIPS data"*, and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined and technical terms accompanied by a supportive explanation in a language suitable for a lay reader. IGARD suggested that section 5 (Purpose / Methods / Outputs) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected"* or *"it is hoped …".* IGARD queried the content of the paragraph in section 5(d) that started *"The benefits of publishing papers…"* and asked that this was updated and edited as appropriate to improve the readability. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 and section 5 with express confirmation that personal data will **not** be shared with the Trusts in order to carry out the processing. **2.** To update section 5 with a brief explanation of how patients may be recruited to the nested consented cohort. 3. To amend section 5 to ensure that all acronyms upon first use are defined and further explained if the meaning is not self-evident., for example, *"Delphi consensus"* and *"CPIPS data"*. 4. To update section 5 to use a form of wording such as "*it is expected"* or *"it is hoped …"*, rather than "*it will…*". 5. To update the paragraph in section 5(d) that starts *"The benefits of publishing papers…"* and edit as appropriate to improve readability.

	6. To update section 5 to ensure references to *"…how patients with Cerebral Palsy are surgically managed..."* are updated to refer to the *"condition"* being managed. 7. To update the reference to the Article 6(1)(e) legal basis in section 5(a) to reflect that this is public task.
2.4	<u>University of Oxford: MR576 - EPIC-Oxford. A prospective cohort study of 65,000 mainly vegetarian men and women, to examine how diet influences the risk of cancer, particularly for the most common types of cancer in Britain, as well as other chronic diseases. (Presenters: Dave Cronin / Denise Pine) NIC-148322-TMFVQ-v7.6</u> **Application:** This was an amendment application to 1) change to the common law duty of confidentiality from section 251 approval to Consent (Reasonable Expectation) for the Hospital Episode Statistics (HES) data; 2) to request HES Admitted Patient Care (APC) from 1997/98 to 2015/16 data to be linked again; 3) a renewal of HES APC data from 2016/17 to the latest available year with annual releases going forward; 4) the addition of NHS number to the demographics product; 5) to add 24 additional fields in Civil Registration (Deaths) data request; 6) a 3 year Agreement as part of this amendment which will include a renewal of Demographics, mortality and cancer data. The purpose is for a study, to examine the effects of diet on long-term health, with a specific focus on vegetarians. The study's overall aim is to provide reliable evidence on choices people can make in adult life to help increase their chances of staying healthy into old age. The aim of the scientific research is to reliably inform the public and health providers and regulators about the statistical findings on risk factors including diet and lifestyle and environmental factors and risk of cancer and other medical conditions. The cohort consist of 60,642 men and women aged 20 and above who were recruited between 1993 and 1999 from throughout the UK. NHS Digital provided IGARD with an overview of the application's history, and in addition, advised that section 3(b) (Additional Data Access Requested) referred to the Civil Registration (deaths) and Demographics data as being both identifiable and pseudonymised. NHS Digital confirmed that this was an error, and both sets of data were identifiable, and that the application would be updated to reflect the correct information. **Discussion:** IGARD thanked NHS Digital for providing an extensive overview of the application history; and noted the error highlighted in 3(b) and supported the necessary updates to accurately reflect that the Civil Registration (deaths) and Demographics data was identifiable. IGARD had a lengthy discussion on the consent materials provided, and confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and were not incompatible with the processing outlined in the application, but made additional commentary as outlined below. IGARD noted the information provided in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs), that specifically referred to views being sought from a participant panel meeting in February 2021; and noting that there was no further information on the exact logistics and make-up of the panel, asked that further details were provided, including, but not limited to, how many panel members were there, how representative are the panel members, and how active are the panel.

	IGARD noted that the most recent consent material, although not incompatible, would need updating further to ensure that they were in line with the NHS Digital DARS Confidentiality Standard. In respect of transparency with the participants, IGARD noted that the applicant had provided a copy of the newsletter from the study website, but queried a number of issues, including, but not limited to, how active the website was, how many active users the website had, and how many views the newsletter on the website had. Noting that this information was not clear, IGARD were therefore unable to assess how effective the website transparency measures were in terms of the UK General Data Protection Regulation (GDPR) transparency requirements. In light of the issues raised, and to ensure there was a clear audit trail, IGARD asked that the applicant produced and provided an action plan as to how the current consent materials would be augmented by way of communication and transparency measures, to bring them in line with the NHS Digital DARS Confidentiality Standard. IGARD advised that they would welcome the transparency action plan coming back to a future IGARD meeting for further discussions. Noting that it is already widely accepted that a healthy diet may lead to better health outcomes, IGARD queried the information provided in respect of the benefits in section 5(d) (Benefits), and in particular, what actual benefits were accruing to patients or the public as information was already widely available regarding the benefits of a healthy diet, and asked that this was updated to expand on this point (for example any specific actions or outputs directly impacting on patients or the public).. In addition, IGARD asked that section 5(d) was also updated, to reflect *how* the benefits would, for example, encourage members of the public to make healthy diet choices, i.e. how the academic outputs have translated into direct impact for patients and / or the general public. IGARD noted the statement in section 5(d) that the study *"…will contribute to reducing the work and cost to the NHS of diet-related ill-health"* and suggested that this was reviewed and amended as appropriate, noting that it was not clear how the study outputs would directly contribute to reduce the cost to the NHS. **Outcome:** recommendation to approve subject to the following condition: 1. To provide an action plan as to how the current consent materials will be augmented by way of communication and transparency measures to bring them in line with the NHS Digital DARS Confidentiality Standard. The following amendments were requested: 1. In respect of section 5(d): a) To update section 5(d) to expand on the benefits accruing directly to patients. b) To review the statement in section 5(d) *"…reducing the work and cost to the NHS…"* and amend as appropriate. c) To update section 5(d) to reflect *how* the benefits will, for example, encourage members of the public to make healthy diet choices, i.e. how the academic outputs have translated into direct impact for patients or the general public. The following advice was given: 1. IGARD advised that they would welcome the transparency action plan coming back to a future IGARD meeting for further discussions.

	It was agreed the condition would be approved out of committee (OOC) by IGARD members, or in meeting, as may be requested by NHS Digital.
2.5	University of Leeds: Improving the safety and continuity of medicines management at care transitions (ISCOMAT): a cluster Randomised Controlled Trial (Presenter: James Gray) NIC-378185-P4L5Z-v0.4 **Application:** This was a new application for a one-off request for pseudonymised Civil Registration (Deaths) data and Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Critical Care, HES Outpatients data, Emergency Care Data Set (ECDS), and Medicines dispensed in Primary Care (NHS Business Services Authority (NHS BSA) data). The purpose is for a programme, with interlinked work packages, which has developed a Medicines at Transitions Intervention (MaTI) toolkit to help the way heart failure patients are supported with their medicines. MaTI was developed through a process of co-design with patients and healthcare staff, with the aim to improve the safety and continuity of medicines at care transitions, and subsequently reduce mortality and readmission to hospital. The MaTI toolkit will be evaluated in the ISCOMAT Trial, which is a cluster randomised controlled trial (cRCT), which randomised 43 secondary care cardiology services (clusters) to implement either the MaTI or continue to deliver their usual care. A total of 1615 men and women aged over 18 years, who were admitted to a participating hospital with a diagnosis of heart failure and evidence of at least moderate left ventricular systolic dysfunction confirmed within the last 5 years, were recruited between June 2018 and March 2020 and consented to share their information. **Discussion:** IGARD noted and commended NHS Digital on quality of the information provided in section 1 (Abstract), which provides historical and additional background information which supported the review of the application by Members. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD queried the role of the University of Bradford, in light of the statement in supporting document 3.1, the patient information sheet, that members of the research team at the University of Bradford would have access to the data. NHS Digital advised IGARD that this was incorrect, and that they had an advisory role and would therefore not have access to the data. IGARD thanked NHS Digital for the verbal clarification, and asked that for transparency, section 1 and section 5 (Purpose / Methods / Outputs) were updated to clarify that staff at the University of Bradford would **not** have access to the data. IGARD noted that the study was funded by the National Institute of Health Research (NIHR), and that funding was in place until 2024, however, noted that the period of funding was for 5 years, and that this commenced in 2017. IGARD therefore asked that either section 1 was updated to address the fact that that the NIHR funding would expire prior to the expiry of the Data Sharing Agreement (DSA), and clarity of how the study would continue without funding; or, that confirmation was provided that the funding was ongoing and sufficient, and that any additional funding documentation was uploaded to NHS Digital's CRM system for future reference. **Outcome:** recommendation to approve The following amendments were requested:

	1. To update section 1 and section 5 to clarify that staff at the University of Bradford will **not** have access to the data. 2. In respect of the funding arrangements: a) To update section 1 to address the fact that that the NIHR funding may expire prior to the expiry of the DSA, and how the study will continue without funding; or, b) To confirm that the funding will be ongoing and sufficient. c) To upload any additional funding documentation to NHS Digital's CRM system.
2.6	University of Nottingham: Protect-CH: Prophylactic Therapy in Care Homes Trial (Presenter: James Gray) NIC-437579-V8J5V-v0.6 **Application:** This was a new application for identifiable Civil Registration (Deaths) data, COVID-19 Second Generation Surveillance System data, Covid-19 UK Non-hospital Antigen Testing Results (pillar 2), COVID-19 Vaccination Status, Demographics, Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (COVID-19), Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Critical Care, HES Outpatients, Secondary Uses Service Payment By Results Accident & Emergency, Secondary Uses Service Payment By Results Outpatients and Secondary Uses Service Payment By Results Spells. The purpose is for a study, that will test one or more treatments with the aim of reducing the risk of care home residents catching the virus that causes COVID-19 and of developing severe disease. The results of the study will rapidly be made available to ensure that treatments can be introduced without delay and COVID-19 guidelines quickly updated. The aim is to set in place a research and governance infrastructure for the efficient delivery of a suite of randomised comparisons to prevent COVID-19 infection and reduce severity/transmission and death in residents in care homes. Only care home residents who gave consent to access their data will be included in the study. **Discussion:** IGARD noted that consent materials[1] had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 27th April 2021. IGARD queried how the points raised at this meeting had been addressed, noting that the points were still relevant, since it was not evident within the application how the previously raised points had been addressed, or if they had been addressed; and asked that section 1 (Abstract) was updated with a brief overview. IGARD confirmed that they were of the view that the **most recent** draft consent materials[2] provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) (see Appendix B) on the 12th May 2021. In respect of **PAG point 1**, IGARD noted that ethical support had not yet been sought, and asked that in line with the NHS Digital DARS Standard for Ethical Approval, written

[1] **Consent materials reviewed on the 27th April 2021** - *SD3.3 Participant ICG V1.0_25Mar2021; SD3.4 Participant IS V1.0_07Apr2021; SD3.5 Legal Rep ICG V1.0_08Apr2021; SD3.6 Legal Rep IS V1.0_0.7Apr2021*.

[2] **Consent materials provided for review for the 13th May 2021 IGARD meeting** (In addition to the documents above) *SD3.7_Participant ICF Draft 0.6 Final v1.0_27 Apr 2021; SD3.8_Participant IS Draft 0.11 Final v1.0_27 Apr 2021; SD3.9_Legal Rep ICF Draft 0.6 Final v1.0_27 Apr 2021; SD3.10_Legal Rep IS Draft 0.6 Final v1.0_27 Apr 2021*

	confirmation was provided that ethical support was in place; and that this was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. In respect of **PAG point 2**, IGARD asked that final versions of the consent materials were provided, and that they should be compatible with the processing outlined in the application. IGARD also requested, that if available, a copy of the consent materials in tracked changes were provided, so it was transparent as to the updates / amendments that had been made to the documents; and that final version of the consent materials were uploaded to NHS Digital's CRM system for future reference. In respect of **PAG point 3**, IGARD suggested that NHS Digital should discuss with the applicant whether there was in fact a risk of type 1 opt-outs being inadvertently revoked. On the basis of the information provided, it was IGARD's view that there was no apparent risk. However, the applicant's attention should be drawn to the fact that any member of the cohort who had type 1 opt-out applied, would not be present in the GDPPR collection that would flow from the GP to NHS Digital, and therefore would not be part of the GDPPR dataset flowing to the applicant. IGARD also suggested that the applicant should ensure that the communication to participating GP's reflected that a cohort member's consent to take part in this study did not in any way affect the continued operation of any type 1 opt-out that may be in place. IGARD queried the inconsistent references throughout the application to the number of care homes involved in the study and asked that section 5 (Purpose / Methods / Outputs) was reviewed and updated throughout, to ensure the narrative in respect of the number of care homes involved in the study was accurately reflected. In addition, IGARD queried the number of groups involved, for example, was this 1 active treatment versus 1 standard care, or 2 active treatment versus 1 standard of care; and asked that further clarity was provided in section 5 since it was not clear. IGARD noted the helpful narrative in supporting document 1.0, the study protocol, that explained the statistical power in respect of the number of care homes involved in the study; and asked that for transparency, section 5 was updated to reflect this information. IGARD noted the final paragraph in section 5(d) (Benefits) that stated: *"Results from this trial **will** inform decisions…"*, and asked that this was updated to more accurately use a form of wording, such as "… *is **expected** to inform decisions…".* In addition, IGARD noted the last sentence in section 5(d) that stated: *"Guidelines and health polices will benefit…"*, and asked that this was updated to more accurately use a form of wording, such as *"it is hoped"*. IGARD queried the references in section 5 to the data being *"anonymised",* and noting that that this was incorrect, asked that this was updated to accurately reflect that data accessed will be *"pseudonymised".* IGARD noted a number of acronyms in section 5, for example, *"GDPPR"*, and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the large volume of data flowing, the potentially vulnerable cohort and the changes to the GP extraction system. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the ethical support:

a) To provide written evidence that ethical support is in place.
b) To upload the written evidence to NHS Digital's CRM system.

2. In respect of the consent materials:
   a) To provide final versions of the consent materials that are compatible with the processing.
   b) To provide a copy of the tracked changes versions of the consent materials if available.
   c) To upload the final version of the consent materials to NHS Digital's CRM system.

The following amendments were requested:

1. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example, *"GDPPR"*.
2. In respect of the number of care homes involved in the study:
   a) To update section 5 with the helpful narrative in the protocol (page 29), to explain the statistical power in respect of the number of care homes involved in the study.
   b) To review section 5 to ensure the narrative in respect of the number of care homes involved in the study is accurately reflected throughout.
   c) To clarify in section 5 the number of groups involved, for example, 1 active treatment vs 1 standard care or 2 active treatment vs 1 standard of care.
3. To update section 5 to accurately reflect that data accessed will be *"pseudonymised"* and not *"anonymised"*.
4. In respect of section 5(d):
   a) To amend the final paragraph in section 5(d) that starts *"Results from this trial **will** inform decisions…"*, to use a form of wording such as "… *is expected to inform decisions…".*
   b) To update the last sentence in section 5(d) that starts *"Guidelines and health polices will benefit…"*, to use a form of wording such as *"it is hoped"*.
5. To update section 1 with a brief overview of how the points previously raised on the consent materials by IGARD on the 27th April 2021 have been addressed.

The following advice was given:

1. In respect of PAG point 3:
   a) IGARD suggested that NHS Digital should discuss with the applicant whether there is in fact a risk of type 1 opt-outs being inadvertently revoked. On the basis of the information provided, it was IGARD's view that there was no apparent risk. However, the applicant's attention should be drawn to the fact that any member of the cohort who has type 1 opt-out applied would not be present in the GDPPR collection that will flow from the GP to NHS Digital, and therefore will not be part of the GDPPR dataset flowing to the applicant.
   b) IGARD suggested that the applicant should ensure that the communication to participating GP's reflects that a cohort member's consent to take part in this study did not in any way affect the continued operation of any type 1 opt-out that may be in place.
2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the large volume of data flowing, the potentially vulnerable cohort and the changes to the GP extraction system.
3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the large volume of data flowing, the potentially vulnerable cohort and the changes to the GP extraction system.

	It was agreed the condition would be approved out of committee (OOC) by IGARD members.
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-147927-8K193-v3.9 University of Birmingham • NIC-148267-W26RZ-v5.4 University of Oxford • NIC-196221-K4K3Y-v1.3 University of Manchester • NIC-50919-D5R5D-v2.2 University of Nottingham & the Swansea University IGARD welcomed the four 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 The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from **Tuesday 11th May 2021** can be found attached to these minutes as Appendix C.
5	<u>Learning and Development Workshop: Data Controllership</u> IGARD noted that on Tuesday 11th May 2021, IGARD hosted a learning and development workshop, for colleagues within NHS Digital's Data Access Request Service (DARS) and Privacy, Transparency and Ethics (PTE) on Data Controllership. The workshop also included looking at specific working example applications which has previously generated lengthy in-meeting discussions; and looked at various published guidance, for example, in the context of university applications. IGARD noted that following the workshop, the IGARD Secretariat had received feedback from a number of NHS Digital's colleagues on this learning session, who suggested future learning and development subject matter. IGARD wished to note their thanks to the large number of NHS Digital colleagues who joined / participated in the workshop, and for the subsequent feedback.

6	General Practice Data for Planning and Research (GPDPR) (Presenters: Arjun Dhillon / Michael Chapman) IGARD noted that on Tuesday 11th May, a suite of 'final' documents (pending any final updates) had been circulated to members, in respect of the GPDPR Programme, which is moving into the next stage of development, in respect of the publication of the Direction and ahead of Thursday's meeting. Dr Arjun Dhillon and Dr Michael Chapman attended the meeting to discuss with members the progress made to date, the anticipated timeline, and next steps. IGARD thanked NHS Digital colleagues involved with this work for sharing the documentation, and to Arjun and Michael for attending the meeting and providing the update and for answering the queries raised by IGARD. IGARD noted and supported the suggestion by NHS Digital that a further meeting be set up in mid-June with regard to the operation of the GPDPR data and that this meeting should include the DARS Head of Service, on behalf of the Associate Director Data Access.
7 **7.1**	AOB: Mental Health Act for consultee (Presenter: Louise Dunn) NHS Digital attended IGARD to provide a verbal update on the ongoing discussions with Health Research Authority Confidentiality Advisory Group (HRA CAG), in respect of the application of the Mental Health Act for consultees. IGARD noted and thanked NHS Digital for the verbal update and looked forward to receiving further information on this issue at a future IGARD meeting. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 07/05/21

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-361800-N8R5G-v0.11	London North West University Healthcare NHS Trust	18/03/2021	1. In respect of data minimisation: a) To update section 3(b) to specify the specific diagnosis codes; or if there are too many to list, to provide a narrative of the codes, directly related to myomectomy. b) To provide a written justification that data for **all** of England is required, and not a representative geographical strata. *(refer to Data Min standard)* c) To provide a justification why 10-years of data has been requested and not a shorter timeframe.	IGARD members	Quorum of IGARD members	IGARD noted the statement added to section 5(b) *"to work as a major strength of this study..."* . IGARD asked that either the sentence was deleted or amended to state something like *"the study's statistical power is improved by having access to data for all of England*", if indeed that's the case.

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

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 120th May 2021

Application & application version number: **DARS-NIC-437579-V8J5V-v0.6** **Organisation name: University of Nottingham** **Profession Advisory Group Agenda item: 2**
PAG support this application subject to the following conditions: 1) Appropriate ethics approval is documented unless this is on the CMO priority list for which PAG would support retrospective evidence. 2) IGARD is satisfied also with the consent material ensuring that the patient is fully informed of the GP data (including retrospective data that would be disseminated). 3) PAG would like assurance that any signed consent material sent to the GP is not inadvertently used to revoke Type 1 Opt Out without further discussion between the GP and patient; it is important that the GP and the patient is made aware that revoking a Type 1 Opt Out would mean their GP data would be available for analysis for any further applications coming through DARS (i.e. their data would not be solely restricted for use in this specific application purpose). Supporting information, which could be part of the consent material shared with the GP and patient, must clearly explain the consequence of revoking a Type 1 Opt Out. 4) Minor amendment to document to change the word 'safely' to 'securely' when referencing the transmission of data.

Attendees	**Role**	**Organisation**
Richard Hatton	Chair, Interim Deputy Caldicott Guardian	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
James Gray	Senior Case Officer	NHS Digital
Pam Soorma	Secretariat	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 11th May 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Maria Clark (Lay Representative)
	Kirsty Irvine (IGARD Chair / Lay Representative)
	Dr. Imran Khan (IGARD Specialist GP Member)
	Dr Maurice Smith (IGARD Specialist GP Member)
In attendance (NHS Digital):	Vicky Byrne-Watts (DARS)
	Liz Gaffney (DARS)
	Dickie Langley (PTE)
	Karen Myers (IGARD Secretariat)
	Vicki Williams (IGARD Secretariat)
In attendance (JBC):	Adam Butler
	Emma French
	Matthew Gillespie
	Will Harmer
	Ross Jones
	Andrew Lethbridge
	Cristian Lungu
	Selina Patel
	Ann-Marie Read
	Nicholas Rhodes
	Claire Sinclair

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 items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix.

	Declaration of interests: There were no declarations of interest.
2.1	Joint Bio Security Centre (JBC) (no NIC number) **Background:** This was an introductory briefing and education session from the JBC **IGARD Observations:** IGARD members welcomed and thanked the JBC team for their verbal overview of their current structure and remit, noting that no discussion had been undertaken on any application that the JBC may submit to DARS (nor any applications previously presented to an IGARD meeting). IGARD members noted that they would welcome further updates via an application to DARS with regard to the future legal bases for collecting, processing and disseminating data; further details of the membership of the Data Science Advisory board; further work around their public engagement; data minimisation efforts being undertaken in line with the DARS Standard for Data Minimisation; and updating / accessibility of relevant privacy notices. In summary, IGARD members looked forward to developing the working relationship with the JBC, alongside NHS Digital. IGARD members noted that this discussion was not to pre-empt discussions on any application that may be presented to a future BAU meeting of IGARD.
3	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.