Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 18 February 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member (item 2.5 – item 6)
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member (item 1 – item 2.4)
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Imran Khan	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
Dave Cronin	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: item 1 - 2.4)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 11th February 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	Royal Papworth Hospital NHS Foundation Trust: Effective Treatments for Thoracic Aortic Aneurysms (ETTAA) (Presenter: Catherine Day) NIC-139146-W7C3P (v0.16) **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) and Civil Registration (death) data. For the period 24th March 2014 to 24th July 2018, 886 patients were recruited to the Effective Treatments for Thoracic Aortic Aneurysms (ETTAA) study, funded by the National Institute for Health Research (NIHR). The proposed project data will allow the validation of the existing study data (collected by local study coordinators), ensuring that dates and causes of death are complete and accurate by linking NHS Digital data, so that any admissions to hospital and key resources used in hospital are reflected accurately in the study data set. It will also facilitate a complete follow up of all patients receiving a procedure in the latter months of the study observation period. The incidence of chronic thoracic aortic aneurysm (CTAA) is rising as the UK population ages and will therefore pose an increasing challenge to health care providers and policy-makers; and based on estimates, there are 3000 – 8000 new cases per year. These patients are at risk of both fatal and non-fatal complications of the condition and the subsequent treatment costs for these patients are high. **Discussion:** IGARD noted that the patients had been consented on a number of different versions of the consent material (v1 = 0, v2 = 19, v3 = 152 and v4 = 715). It was clear, however, that v2 of the consent materials was incompatible with the processing outlined in the application and that those 19 patients who were consented under v2 of the consent materials should be either written to and informed of the change in processing as outlined in later consent materials; or that the 19 patients should not be included in the study and no data would flow for them. IGARD suggested that the application be updated to reflect the decision taken by the applicant with regard to those 19 patients consented on v2 of the consent materials. In addition, and should the applicant wish to retain the 19 patients in the study, that NHS Digital may wish to consider offering a list cleaning, so as not to add any undue stress to the family, should a patient have died, and that IGARD would be supportive of this action. IGARD were content that v3 and v4 of the consent materials were compatible with the processing outlined in the application. IGARD noted reference in section 5(b) (Processing Activities) to a researcher who had recently moved to the London School of Hygiene and Tropical Medicine (LSHTM) and that a contract was in place; but asked that an express statement be included in section 5 (Purpose / Methods / Outputs) that only those researchers from LSHTM under an honorary contract would have access to the data under this application, and that no other access to the data by the LSHTM was allowed. IGARD noted in section 5a (Objective for Processing) reference to "*resource use*…" and suggested the section be written in a language suitable for a lay reader and technical terms used only where necessary. 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.

	In addition, IGARD suggested removing reference to supporting documents "*SD6.0 and SD6.1*" in section 5(b) since they were not publicly available or to provide a link to the documents, if available. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…" IGARD noted in section 8b (Funding Sources) that the "*Secretariat of State for Health*" had been listed as the awarding institution and suggest that this was updated to more accurately reflect that it was the NIHR. **Outcome:** recommendation to approve for those participants consented on v3 and v4 of the consent materials and unable to recommend for approval for those participants consented on v2 of the consent materials. The following amendments were requested: 1. To make any amendments as necessary to the application to reflect the fact that cohort members consented on v2 will either be; a. written to and informed of the change in processing as outlined in the later consent materials, since v2 is incompatible with the proposed processing; OR b. will **not** be included in this study and therefore no data will flow for those 19 participants. 2. To update section 5 to expressly state that only researchers from LSHTM under a honorary contract will have access to the data under this DSA (and there is otherwise no access to the data by LSHTM). 3. To amend section 8(b) to ensure the "awarding institution" accurately reflects the correct funder details. 4. To update section 5(b) to remove the reference to any "*supporting documents*" or to provide a publicly accessible link. 5. To explain what is meant by the reference to "*resource use…*" in section 5. 6. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident. 7. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*"
2.2	<u>Manchester University NHS Foundation Trust: Prospective Triage HF+ Evaluation: What is the workload burden associated with using the Triage HF+ care pathway? (Presenter: Catherine Day) NIC-401890-W6Q8W</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES), Civil Registration (death), and Emergency Care Data Set (ECDS); for the purpose of a study, to establish the workload burden associated with the newly developed clinical pathway "Triage-HF Plus"; with patients being recruited from three hospital sites across North West England, with an initial recruitment target of a single cohort of 450 participants. The TRIAGE study follows on from the project "*Triage-HF Plus: Cardiac Implantable Electronic Device Remote Monitoring Combined with Telephone Triage to Identify and Manage Worsening Heart Failure" known as the "Retrospective TRIAGE*" which was supported by s251 support. The pathway uses a risk score generated from implanted cardiac devices (Heart Failure Risk Score "HFRS") to guide a remote monitoring service, where patients identified at 'high' risk of

	decompensated heart failure are telephoned by clinical staff in an attempt to 1) diagnose and treat issues early in the course of illness and 2) reduce risk of hospitalisation. An important part of evaluating this pathway is to establish the burden of implementing the pathway on the provider, an essential part of health economic analysis; and the secondary objectives of the TRIAGE study include exploration of the relationship between clinical pathway and events. **Discussion:** IGARD noted that the TRIAGE study had informed patient consent and that the consent materials provided were compatible with the processing outlined in the application, however, noting the population make-up of Manchester and that consent materials were provided only in English and that consent should only be provided in English, IGARD members suggested this may be a barrier to participation, and that thought be given to ensure inclusivity for the benefit of the whole population (See AOB). IGARD noted a number of acronyms in section 5 (Purpose / Methods / Outputs) and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader. IGARD noted the recent update from NHS Digital and asked that section 1 (Abstract) and section 5 were updated to reflect the recent update to the HES Analysis Guidelines in respect of the change to the cut off point for small number suppression and the potential impact across a number of audits. IGARD noted in section 5(a) (Objective for Processing) reference to "*industrial partner*s" and suggested that this was updated to "*commercial partners*" as outlined in NHS Digital's DARS Standard for Commercial Purpose, noting that in academia, they may refer to partners as being *"industrial"* rather than *"commercial"*. **Outcome:** recommendation to approve 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 to a general audience. 2. To update section 1 and section 5 to reflect the recent update to the HES Analysis Guidelines in respect of the change to the cut off point for small number suppression 3. To amend the reference in section 5(a) from "*industrial partner*" to "*commercial partner*", in line with NHS Digital's Standard Commercial Purpose.
2.3	<u>University of Surrey: The dynamics of frailty in older people: modelling impact on health care demand and outcomes to inform service planning and commissioning (Presenter: Vicky Byrne-Watts) NIC-353126-Y1S5F (v0.16)</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) and Civil Registration (death) data; for the purpose of a study, exploring trends in development and progression of frailty; and the dynamics of frailty related healthcare demand, outcomes and costs in the older general practice population, to inform the development of guidelines and tools to facilitate commissioning and service development for this patient group. The study comprises 4 workstreams, with this application relating specifically to Workstream 1: "*statistical modelling of population trends, incidence and prevalence of frailty, stratification of frailty and related outcomes, resource use and costs*", and Workstream 4: "*simulation*

	modelling to explore impact of different service and demographic scenarios on population trends, service demands and costs in the future". NHS Digital noted that section 1 (Abstract) should be updated to reflect that both workstreams 1 and 4 were part of this application, since only Workstream 1 was currently listed. **Discussion:** IGARD noted the update from NHS Digital that Workstream 4 narrative would be included in section 1, alongside the narrative with regard to Workstream 1. IGARD also noted that Workstreams 2 and 3 were not part of this application. IGARD also noted that the application would be moving from the University of Surrey to the University of Oxford and that appropriate narrative be included in section 1 (Abstract), for future reference. IGARD noted that NHS England Electronic Frailty Index (eFI) uses existing information within the electronic primary health care record to identify populations of people aged 65 and over who may be living with varying degrees of frailty. IGARD noted that since it was a population risk stratification tool, that a further explanation be provided in section 5 (Purpose / Methods / Outputs) as to how clinical diagnosis would be undertaken, using this Index. In addition, and noting that the Index was primarily for those aged 65 to 95 years of age, IGARD were unclear how the eFI would be utilised to stratify the cohort agenda 50 to 65 years of age, since the applicant would not have the 36 variables necessary for the tool, and that further clarification be included in section 5. Noting that the eFI tool cannot be used to identify varying degrees of frailty in individuals, as set out in the published Index, IGARD asked that further clarification be given in section 5 as to how the eFI tool would be used to identify individual frailty. Finally, IGARD noted that for those aged 65 and older, that the eFI tool would include a great deal of coding variability due to how frailty was captured by the GP, for example. Noting that "*RCGP*" (Royal College of GP's) was being used as shorthand throughout the application when referring to the Research Surveillance Centre (RSC), IGARD asked that the application be updated throughout, and as appropriate, to fully reference "*RCGP RSC*". IGARD suggested that the data minimisation column in section 3(b) (Additional Data Requested) be updated to reference the approximate cohort number of 2.2 million, in line with NHS Digital's DARS standard for Data Minimisation. 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. In addition that section 5(a) (Objective for Processing) should be written in Plain English and in a language suitable for a lay reader, or to provide appropriate lay summaries to explain, for example, the statistical terms outlined. Noting that section 5 serves as NHS Digital's public facing release register, that the length of the section (over 4 pages) also be reviewed in order to be more readily accessible. Finally, IGARD noted a couple of typos which altered the meaning of the sentence and which should be updated in section 5(a) and in addition, that any repetitive text be removed. IGARD suggested that section 5(b) (Processing Activities) be updated to ensure that where appropriate the term *"gender"* was replaced with the term *"sex"* to reflect the available field in the data set requested. IGARD noted reference to the relevant public and patient involvement with the study and in particular to the to the engagement groups outlined in both section 5(b) and 5(c) (Specific Outputs Expected, including target dates), however it was unclear if the "*study engagement*

	group" and "*stakeholder engagement group*" were the same entity and asked that either the terminology was updated to clearly identify them as the same "group", or to provide a clear narrative to distinguish the tasks undertaken by each of the engagement groups. IGARD noted that section 5(d) (Benefits) should be updated in line with NHS Digital's DARS standard for Expected Measurable Benefits including, but not limited to, ensuring that section 5(d) only contained the benefits relating to the Workstreams 1 and 4, as outlined in the application; and be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…" **Outcome:** recommendation to approve subject to the following condition: 1. With reference to the data request for those in the cohort aged 50 to 64: a. To provide a clarification in section 5 as to how the eFI tool will be utilised to stratify a cohort aged 50 to 64, since they would not have the 36 variables necessary for the tool. b. Since the eFI tool is a population risk stratification tool, to clarify in section 5 how clinical diagnosis will be undertaken. c. To clarify in section 5 how the eFI tool will be used to identify individuals, since the eFI tool cannot identify varying degrees of frailty in individuals. The following amendments were requested: 1. To update the application throughout to be clear that where referencing "*RCGP*" it should be updated, where appropriate to fully reference "*RCGP RSC*". 2. To update the data minimisation column in section 3(b) to give an approximate number of cohort members. 3. To amend section 5 to ensure that all acronyms or abbreviations upon first use be defined and further explained if the meaning is not self-evident. 4. In respect of section 5(a): a. To ensure it is written in Plain English and in a style suitable for a lay reader, or to provide appropriate lay summaries to explain for example the statistical terms outlined. b. To edit the length of the section in order for it be more readily accessible, noting section 5 serves as NHS Digital's public facing data release register. c. To amend any typos, which may alter the meaning of a sentence. 5. To ensure that the datasets requested align with the specific NHS Digital data that can flow, for example requesting 'sex' rather than 'gender' if "sex" is what is captured in the dataset. 6. In respect of the engagement groups outlined in section 5(b): a. To clarify if the "study engagement group" and the "stakeholder engagement group" are the same; if not b. To provide a clear narrative to distinguish the tasks carried out by both engagement groups. 7. In respect of the benefits in section 5(d): 1. To update section 5(d) to ensure **only** the benefits are reflected relating to the two workstreams outlined in the application. 2. To update section 5(d) to note that "*it is hoped* …", rather than "*it will*…", in light of the limitations of eFI. 3. To ensure the benefits comply with NHS Digital's Expected Measurable Benefits Standard 5(d). 8. In respect of section 1: a. To include reference to workstream 4 (currently only reference workstream 1).

	b. To reference that the application will be moving from the University of Surrey to the University of Oxford. The following advice was given: 1. IGARD noted that for those aged 65 and over, the eFI tool would include a great deal of coding variability. It was agreed the condition would be approved out of committee (OOC) by IGARD Members
2.4	Group Application 4 x General Practices [1]: DSfC - Grand Union PCN - Population Health Management (Presenter: Duncan Easton) NIC-408298-F5K8J (v0.4) **Outcome:** The application was withdrawn by presenter.
2.5	Office for National Statistics (ONS): Investigating COVID-19 (Presenter: Dave Cronin) NIC-400304-S1P1B (v2.2) **Application:** This was a renewal and extension application for identifiable Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (COVID-19) (GDPPR) and Hospital Episodes Statistics (HES) data. It was also an amendment to 1) change the legal basis for the dissemination of the data; 2) to change the purposes for processing the data to permit a broader scope of research / analysis in response to emerging questions about the COVID-19 pandemic; 3) to add another purpose for processing the data concerning an analysis of data quality of ethnicity information in different data sources. ONS requires data for three purposes all relating to the COVID-19 pandemic: 1) **Emerging questions relating to COVID-19** – providing rapid responses to the COVID-19 pandemic on emerging research questions which are arising as the pandemic continues and as understanding of COVID-19 and its impact increases. This work is to support the ongoing government response and has been requested by central government leaders and advisors such as SAGE and the government, via the National Statistician. 2) **QCOVID analysis** - to urgently quality assure a QCOVID algorithm developed by the University of Oxford to identify clinical vulnerability to COVID-19. This algorithm will be used operationally by Public Health England as a replacement for the previously used shielding list. 3) **Investigating quality of ethnicity data** - reporting by ethnicity has become increasingly apparent as a key requirement to help understand inequalities during the COVID-19 pandemic. NHS Digital noted that due to an administration error, the application had not been included on the Profession Advisory Group (PAG) agenda for Wednesday, 17th February but had been included as an agenda item for the following Wednesday, and that any IGARD support would be conditional, as per the agreed process. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 8th and 15th September 2020. IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 9th September 2020 (and that notes from this meeting had been attached to the IGARD minutes from the 17th September 2020); and the 18th November 2020 (and that notes from this meeting had been attached to the IGARD minutes from the 19th November 2020).

[1] Baldwins Lane Surgery, Bridgewater Surgeries, Garston Medical Centre, New Road Surgery

	IGARD noted the update from NHS Digital but confirmed that they would require requisite PAG support and noted that application would be presented at the PAG meeting on Wednesday 24th February 2021. IGARD asked that written confirmation should be provided, by way of a copy of PAG's minutes, and that PAG should have given their full support to the application; or should PAG require further information or assurances that confirmation be provided that PAG had been satisfied. In addition, IGARD asked that this documentation be uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD queried if NHS Digital's Privacy, Transparency and Ethics (PTE) Directorate (formerly the Information Governance Directorate) had reviewed the change in legal basis and NHS Digital confirmed that they had not. IGARD suggested that written confirmation be provided that PTE were content with the change in the applicant's legal basis and that all the proposed processing as outlined in this application aligned with the production of official statistics. In addition, that section 5 (Purpose / Methods / Outputs) of the application, which forms part of the publicly available NHS Digital data release register, was updated to expressly state that all the data requested was necessary for the production of official statistics. IGARD also asked that all relevant documentation was uploaded to NHS Digital's CRM system for future reference. Noting that the applicant wished to change their legal basis from Regulation 3(4) of the Health Services Control of Patient Information (COPI) Regulation 2002 to section 45(a) of the Statistics and Registration Service Act (SRSA) 2007, which would entail the National Data Opt-Out (NDO) **not** being upheld, IGARD suggested that urgent attention should be given to the transparency materials available to citizens, who, when exercising their NDO, may be unaware that the NDO does not apply in the production of official statistics by ONS. In addition, it should be made clear to citizens that ONS regard the production of official statistics has having a wide scope, encompassing such activities as the research purposes within this data sharing agreement (DSA) / application. IGARD noted that future consideration be given, if and when researchers would have access to the data under this DSA, to the fact that the NDO had **not** been applied because the data was classed as production of official statistics. IGARD also raised the important point that if the data had flowed for research purposes, the NDO would have been applied, and would be applied if the same data was accessed from other sources. IGARD reiterated their comment made on the 19th November 2020 that, in their view, ethical review should be sought, and queried if the application had been presented to ONS's quarterly National Statistician's Data Ethics advisory Committee (NSDEC) on the 17th February 2021. If the application **had** been presented to NSDEC, then written confirmation should be provided that a briefing on the application had been presented on the 17th February and that no substantial points had been raised. If the application **had not** been seen by NSDEC on the 17th February, IGARD asked that confirmation be provided that the application had been scheduled on the Committee's next available agenda for consideration. In addition, IGARD asked for a special condition be inserted in section 6 (Special Conditions) that ONS would furnish NHS Digital with a written copy of NSDEC's approval when issued and that the documentation be uploaded to NHS Digital's CRM system for future reference. IGARD noted the amendment to include analysis of data quality of ethnicity information in the different data sources and were very supportive of this valuable exercise, in the current climate. IGARD noted the limited yielded benefits listed in section 5(d) (Benefits) (iii) (Yielded Benefits) and noting NHS Digital's DARS Standard for Expected Measurable Benefits, suggested that

	the applicant update this section to give a brief summary of specific yielded benefits that have flowed using this data, for example the applicant could reference the positive work highlighted in the national news with regard to the validation of the QCOVID data and consequent additions to the Shielded Patient List (SPL). IGARD also noted that the link provided in section 5(d) appeared to be "broken" and that this should be updated to ensure it worked across a variety of internet platforms. **Outcome**: recommendation to approve subject to the following conditions: 1. In respect of the requisite PAG support: a) To provide written confirmation, by way of a copy of their minutes, that PAG have given their full support for this application; OR b) Should PAG request further information or assurances, that confirmation be provided that PAG have been satisfied; and c) To upload the written evidence to NHS Digital's CRM system. 2. In respect of the change to the applicant's legal basis: a) To confirm in writing that NHS Digital's PTE Directorate are content with the change of legal basis and that all the proposed processing aligns with the production of official statistics; and b) To update section 5 to expressly state that all the data requested is necessary for the production of official statistics; and c) To upload the written evidence to NHS Digital's CRM system. 3. In respect of the ethical approval to either: a) Confirm that the NSDEC considered the application at their quarterly meeting on the 17th February 2021; OR b) To confirm that NSDEC received a briefing on the application at their quarterly meeting on the 17th February 2021 and did not raise any substantial points; OR c) To confirm that the application has been scheduled on the next NSDEC agenda for consideration. The following amendments were requested: 1. In respect of the ethical approval: a. To insert a special condition in section 6 that ONS will furnish NHS Digital with a copy of NSDEC's approval when issued. b. To upload the written evidence to NHS Digital's CRM system. 2. In respect of the section 5(d)(iii) Yielded Benefits: a. To provide an updated brief summary of specific yielded benefits that have flowed from the use of this data, for example the work highlighted positively in the national news around the validation of QCOVID data and consequent additions to the SPL. b. To update the web link provided to ensure it was accessible across a range of internet providers. c. To ensure the yielded benefits comply with NHS Digital's DARS Standard for Expected Measurable Benefits. The following advice was given: 1. Given the reliance on the proposed legal basis will entail the NDO not being upheld, IGARD suggested that urgent attention is given to transparency material available to citizens, who when exercising their NDO would probably not be aware that the NDO would not be applied in the production of official statistics by ONS. In addition, that it be

	made clear to citizens that ONS regard the production of official statistics has having a wide scope, such as the research encompassed by this application. 2. IGARD raised an issue for future consideration: if and when researchers have access to data under this DSA, that consideration should be given to the fact that the NDO has not been applied because it is classed as production of official statistics. Conversely, if the data had flowed for research purposes, that NDO would have been applied (and will be applied if the same data is accessed from other sources). It was agreed the conditions would be approved out of committee (OOC) by IGARD members
2.6	<u>Civil Eyes Research Ltd: HES data application (Presenter: Dave Cronin) NIC-35166-B5Y7P (v5.5)</u> **Application:** This was a renewal and extension application for pseudonymised Hospital Episodes Statistics (HES) data; and an amendment, to 1) receive Emergency Care Data Set (ECDS) as a replacement for HES Accident & Emergency data; 2) to edit / remove an element of the previously approved purpose; 3) to request data on a monthly frequency rather than on an annual frequency. The purpose of the processing operation is to provide analysis and interpretation of performance and quality issues within healthcare to doctors, clinicians and managers of NHS and Social Care providers; and to support the proper administration and facilitation of benchmarking activities. NHS Digital noted that supporting document 1, the data flow diagram, had been provided but was not relevant to the review and had been subsequently removed from the folder on NHS Digital's customer relationship management (CRM) system. NHS Digital noted that section 7 (Approval Consideration) incorrectly referenced supporting document 1, the data flow diagram, which was no longer relevant to this application and had been subsequently updated within the application. NHS Digital noted that section 3(b) (Additional Datasets Requested) incorrectly referenced the data as being *"sensitive"* and that this had been subsequently updated, since the data was **not** classed as sensitive. NHS Digital noted that data retention date in section 8(a) (Data retention: indicative data retention period" of *"10/03/2021"* was incorrect and would be updated in line with the data sharing agreement (DSA) expiry date. **Discussion:** IGARD noted the update from NHS Digital and that the application had been updated with regard to supporting document 1, data being incorrectly classed as *"sensitive"* and the update to the retention period in section 8. IGARD noted reference in section 6 (Special Conditions) to "*a maximum of five years data will be retained at any point…*" and suggested this was updated to reflect the move to monthly dissemination of data. IGARD noted reference in section 5(a) (Objective for Processing) to the "*pathology network*" and suggested that application be updated to reflect that the benchmarking programmes have been reduced from three programmes to just two: "*medical productivity*" and "*specialist children's hospitals*". Noting NHS Digital's DARS Standard for Expected Outputs, IGARD suggested that further narrative be included in section 5(c) (Specific Outputs Expected, including target dates)

	including, but not limited to, clearly explaining how the outputs translated into benefits for patients and patient care. Noting NHS Digital's DARS Standard for Expected Measurable Benefits, IGARD asked that section 5(d) (Benefits) be updated to include, but not limited to, removing the long list of narrative provided in section 5(d) (iii) (Yielded Benefits) and instead replace this long list with a brief summary of several specific yielded benefits that have flowed from the use of this data. In addition section 5(d) should include a narrative as to how each of the benefits provided have accrued to patients and / or patient care. IGARD also noted duplicated text across section 5(d) and suggested that this be reviewed and removed, where necessary. IGARD noted that the addresses listed in sections 2(a) (Processing Location(s)) and 2(b) (Storage Location(s)) appeared to be the same residential address and asked NHS Digital to ensure these addresses aligned with those provided as part of the Data Security and Protection Toolkit (DSPT) review. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the special condition in section 6 to reflect the move to monthly dissemination of data. 2. To amend the application throughout to reflect that the benchmarking programmes have been reduced to two programmes, from three. 3. To provide a further narrative in section 5(c) to explain how the outputs translated into benefits for patients and patient care, as per NHS Digital's DARS Standard for Expected Outputs. 4. In respect of section 5(d): a) To remove the long list narrative provided in section 5(d)(iii) and include a brief summary of several specific yielded benefit(s) that flow from the use of this data b) To update section 5(d) to include narrative as to how the benefits accrue to patients and / or patient care. c) To review and remove any duplicated text. d) To ensure the benefits comply with NHS Digital's Expected Measurable Benefits Standard. 5. To ensure that the storage and processing locations listed in section 2 align with those that were provided as part of the DSPT review.
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-44356-Y8N6R-v5.2 HQIP • NIC-382364-Y0F4F-v0.8 University of York • NIC-194629-S4F9X-v2 The Nuffield Trust • NIC-147940-WVXJF-v3 University of Oxford 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	IG Covid-19 Release Register January 2021 IGARD noted that the IG Covid-19 Release Register January 2021 had been circulated and reviewed out of committee by members, and discussed and agreed the comments that would be shared with the Privacy, Transparency and Ethics Directorate.
5	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 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 16th February 2021 can be found attached to these minutes as Appendix B.
6 **6.1**	AOB: COPI Notice Extension and GDPPR applications Following the extension of The Health Service Control of Patient Information (COPI) Regulations 2002 until the 30th September 2021, NHS Digital noted that there were a number of applications that had been progressed on the basis of the original COPI notice end date of 31st March 2021, and so all CCG GP Data for Pandemic Planning & Research (GDPPR) applications under template and GDPPR research applications with this end date would be updated to end on the 30th September 2021. No other changes would be made to the applications. NHS Digital noted that since these are minor changes to extend the applications, they would not be submitted to either the Profession Advisory Group (PAG) or IGARD for consideration. IGARD were content with this approach, but noted to NHS Digital that a quick check of the relevant applications be undertaken to see if there were any additional requirements for a 6 month extension, for example, renewed ethical support, relevant security assurance, special conditions to update and any public communication indicating the processing would cease on the 31st March 2021.
6.2	Consent and insistence on written informed consent in English Noting item 2.2 above, (NIC-401890-W6Q8W Manchester University NHS Foundation Trust where consent materials had only been provided in English and that the trial had asked that consent be provided in English), IGARD noted that this could be viewed as NHS Digital enabling the systematic exclusion of sections of the population (for example the illiterate) and indirect racism (with fluency in English likely to vary between ethnic groups). This is not the first time IGARD has noted this issue and members asked how this could be advanced with

	the Health Research Authority, for those applications that had ethical approval, and further thought be given to ensure equity for the benefit of the whole population, particularly where an application was being funded by the taxpayer, but noting that any such exclusion will lead to data bias (and consequently further health inequities) regardless of the nature of the funding source.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 12/02/21

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-300282-G9Q0Q	University College London	10/12/2020	1. In respects of UCL: a) To provide a justification in section 5(a) why UCL (listed as a Data Processor) are continuing to hold the data and how it relates to the processing outlined in this agreement and how UCL is under the instruction of one or both of the Data Controllers. b) To confirm whether the purpose of this application permits UCL to retain the data which they received under application NIC-115405-P6X6Q. c) To remove reference to UCL being a “Data Guardian” in section 5(a).	IGARD members	Quorum of IGARD members	None
NIC-396119-C8W3W	University of Oxford -	03/12/2020	1. To provide a clear justification in section 5(a) why the datasets are required (which aligns with NHS Digital’s DARS Objective for Processing Standard). 2. In respect of the mortality data requested:	IGARD members	Quorum of IGARD members	None

			a) To update section 5(a) with a specific justification as to why mortality data is required. b) If mortality data is not required, to update the application to remove references to this data.			
NIC-324170-J4P1J	King's College London Hospital NHS Foundation Trust	21/01/2021	1. To provide confirmation of the role of King's College London (the University) in this application, noting that they have been referenced as a Data Controller in the PREDICT transparency materials.	IGARD members	Quorum of IGARD members	None

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

Appendix B

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 16th February 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Dr. Imran Khan (IGARD Specialist GP Member)
	Dr. Geoff Schrecker (IGARD Specialist GP Member / IGARD Deputy Chair)
In attendance (NHS Digital):	Dan Goodwin (DARS)
	Richard Hatton (Clinical Informatics and Deputy Caldicott Guardian (ai))
	Karen Myers (IGARD Secretariat)
	Kimberley Watson (DARS)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Deputy Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** There were no declarations of interest.
2.1	NIC-388913-L5D5B v1.2 Group application for 10 CCGs[2] **Background:** This was a business as usual (BAU) application (v1.2) to amend the group application for 10 CCGs to allow the CCG to re-identify patients where there was a need to do so for direct care purposes. The identifiable data would only be shared with those health professionals who had a legitimate relationship with the patient and legitimate reason to access the data. The application and relevant supporting documentation had been previously presented at the COVID-19 response meeting on the 9th February 2021.

[2] NHS Trafford CCG; NHS Oldham CCG; NHS Tameside and Glossop CCG; NHS Stockport CCG; NHS Bury CCG; NHS Wigan Borough CCG; NHS Bolton CCG; NHS Heywood, Middleton and Rochdale CCG; NHS Manchester CCG; NHS Salford CCG

	NHS Digital noted that since its presentation at the COVID-19 response meeting, additional information had been provided with regard to the re-identification amendment. NHS Digital noted that the application and relevant supporting documentation had not been presented to the Profession Advisory Group (PAG) last Wednesday, but would be presented at tomorrow's meeting. **IGARD Observations:** IGARD members noted the update from NHS Digital and that the application was to be presented at PAG on Wednesday, 17th February and an IGARD business as usual (BAU) yet to be determined. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on a Thursday and thanked NHS Digital for their verbal update. **Significant risk area:** Using GDPPR data to provide direct care may present significant risks due to the complexities of how GDPPR data is derived from the GP clinical systems in terms of both the application of type 1 objections and the time scales of the data flows (it flows from the GP clinical system to NHS Digital, then from NHS Digital to the CSU, then from the CSU to the CCG, before flowing back to the GP). IGARD members suggested that they would be available to support the applicant further, since it appeared that a GP practice could be working with GDPPR data that would not be as up to date as the GP system, which may present a clinical risk to their patients.
2.2	<u>NIC-434738-K7Z9L-v0.3 Office for National Statistics (ONS)</u> **Background:** this was a new application (v0.3) requesting new demographics data for the over 80's COVID-19 vaccination survey. During the national COVID-19 SARS-CoV-2 vaccination programme, patients in England who were aged 80 years or over were offered a vaccination as part of cohort 2, as detailed by the Joint Committee on Vaccination and Immunisation (JCVI). The ONS would like to survey a sample of those persons aged 80 years and over in order to gather behavioural insight and attitude information of individuals that are likely to have been offered the vaccines to inform public messaging around vaccinations and public health strategies. The following observations were based on the basis of the application summary and relevant supporting documentation only. NHS Digital noted this was an urgent request that had already progressed last week via the NHS Digital SIRO precedent. NHS Digital noted the likelihood of amendments to request further flows of data for more cohorts as the programme rolls out. **IGARD Observations:** IGARD members noted that this was an important study and were supportive of the application. Noting that the application had already proceeded via the NHS Digital SIRO precedent but that further amendments may be made to the application and that it may be presented to a future IGARD business as usual (BAU) meeting, IGARD noted the following: 1. With reference to the request for telephone number:

	a. To ensure that the provision of the telephone number is compatible with data minimisation (as set out in NHS Digital's DARS Standard for Data Minimisation) given that the invitation letter is presumably asking for participants to provide a contact number to be telephoned on. b. To note that for those patients who do not have a telephone number on the system, that this may be a marker for a small cohort of participants who may require a different approach in order to reach them. 2. With reference to the Data Protection Impact Assessment (DPIA) provided as a supporting document: a. To update the legal basis cited in the DPIA from s45A of the Statistics and Registration Service Act 2007, to that listed correctly in the application, namely the Health Service Control of Patient Information Regulations 2002 (COPI) (Regulation 3(3) and 3(1)) b. To update the DPIA reference to "consent" being the legal basis, to that correctly listed in the application, namely Articles 6 and 9. c. To clearly set out under each UK General Data Protection Regulation (UK GDPR) legal basis cited, the different types of processing of the data being undertaken. d. To remove reference from the DPIA to "a*ll data processors have GDPR compliant DPAs…*" since this is not relevant to the application. 3. To clarify whether the contact data should be combined with the vaccine data as to whether patients had been vaccinated to enable relevant stratification. 4. To clarify what or who the "OPN" cohort is, as noted in the application. 5. To ensure that the application of the National Data Opt-Out (NDO) is consistent with other surveys, for example the cancer surveys where NDOs are not applied.
2.3	<u>Proxy Access for Children – Discovery Commissioned by NHS X</u> **Background:** this was a verbal update by the Deputy Caldicott Guardian (ai) with regard to a planned discovery exercise commissioned by NHS X seeking independent advice as to whether during the discovery phase, the relevant questions were being asked. **IGARD Observations:** IGARD members welcomed the early discussion and suggested that they would be available to support NHS Digital further with the discovery phase or further work, as deemed appropriate.
3	<u>AOB</u> There was no further business raised, the IGARD Deputy Chair thanked members and NHS Digital colleagues for their time and closed the meeting.