IIndependent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 11 February 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Dave Cronin	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Liz Gaffney	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 1 - 2.3)
Denise Pine	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Aneesah Shahpal	Data Access Request Service (DARS) (Observer: items 1 - 2.6)
Tracy Taylor	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Maria Clark noted professional links to the University of Sheffield (NIC-116377-L5J9M), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 4th 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	<u>National Institute for Cardiovascular Outcomes Research: National Audit for Percutaneous Coronary Interventions (Angioplasty) - HES Tabulation data (Presenter: Frances Hancox) NIC-318886-M1B9L (v1.3)</u> **Application:** This was a renewal and extension application for aggregated Hospital Episodes Statistics (HES) data; and an amendment to 1) remove Redcentric PLC as a storage and processing location; 2) to update section 5(c) to reflect revision in the target date of expected outputs, and 3) to update section 5(d) (iii) to add new yielded benefits. The Healthcare Quality Improvement Partnership (HQIP) has commissioned, on behalf of NHS England as part of the National Clinical Audit and Patient Outcomes Programme (NACPOP), six national cardiovascular audits which are managed by the National Institute for Cardiovascular Outcomes Research (NICOR). The aim of these National Cardiac Audit Programme (NCAP) audits is to measure and report delivery of care against defined guidance standards and to enable the improvement of the quality of care and outcomes of patients with a range of cardiac conditions. The data will be used to produce participation tables for audit purposes and to determine whether hospitals are fully participating in the audit. **Discussion:** IGARD queried the statement in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) *"If numbers were suppressed, comparison to HES figures with the number of records that hospitals have submitted would result in NICOR numbers being inaccurate. i.e. If 300 cells are suppressed, that is up to **1500** admissions excluded from the total…"*, and were advised by NHS Digital that the HES Analysis Guidelines had been updated, whereby previously the cut off point for small number suppression was below 5, this had recently changed to suppression of small numbers from to 1-7. Zeros do not need to be suppressed. NHS advised that the 1500 stated, may have therefore been calculated on the old guidance. IGARD noted the update from NHS Digital and asked that section 1 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 also noted the useful description in section 6 (Special Conditions), that clearly described how the HES Analysis Guidelines worked, and asked that this was replicated in the public facing section 5(b) (Processing Activities).

	IGARD queried the benefits outlined in section 5(d) (Benefits), noting that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and that these were added to section 5(c) (Specific Outputs Expected) instead. In addition, IGARD noted that once the outputs had been moved to section 5(c), the information that remained in section 5(d) did not specifically refer to many benefits, and asked that this was updated to ensure that **only** the benefits were reflected; and that the benefits listed complied with NHS Digital's Expected Measurable Benefits Standard 5(d). IGARD also noted that page 33 of the National Cardiac Audit Programme Annual Report 2020 that was published in December 2020, highlighted some excellent yielded benefits, and asked that these were replicated in section 5(d) (iii) (Yielded Benefits) for transparency and future reference. IGARD noted that the Healthcare Quality Improvement Partnership (HQIP) had a privacy notice, however advised that this was difficult to locate online, and suggested, that to ensure compliance with the UK General Data Protection Regulation (GDPR), that this was made more readily accessible to the public. **Outcome:** recommendation to approve The following amendments were requested: 1. 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 and the potential impact across a number of audits. 2. To replicate the special condition from section 6 into section 5(b), which adds a useful description of how the HES Analysis Guidelines work. 3. To remove any specific outputs from section 5(d) and move to section 5(c). 4. In respect of the benefits in section 5(d): a) To update section 5(d) to ensure **only** the benefits are reflected. b) To ensure the benefits comply with NHS Digital's Expected Measurable Benefits Standard 5(d). c) To replicate some of the yielded benefits outlined in the National Cardiac Audit Programme Annual Report 2020 Report (p33) published in December 2020, in section 5(d) (iii). The following advice was given: 1. IGARD noted that HQIP has a privacy notice, however advised that this was difficult to locate online, and suggested that to ensure compliance with the UK GDPR, that this is more readily accessible to the public.
2.2	<u>Department of Health and Social Care: MR1376 - OHCAO (Out of Hospital Cardiac Arrest Outcomes) (Presenters: Dave Cronin / Frances Hancox) NIC-365132-V5S8H (v1.1)</u> **Application:** This was a renewal and extension application for pseudonymised Hospital Episodes Statistics (HES), Mental Health Services Data Set (MHSDS) and Maternity Services Data Set (MSDS). The NHS Digital Portal / Data Access Environment (DAE) enables organisations to access data for a wide range of data analytical purposes. The system is an online analytical processing tool through which the users of this organisation data have access to a wide range of analytical, graphical, statistical and reporting functions. The applicant will use the NHS Digital Portal / DAE through the analysis of data as listed in this Data Sharing Agreement

	(DSA), in support of the Secretary of State for Health in delivery of their duties set out within the National Health Service Act 2006. **Discussion:** IGARD noted the limited information provided, in respect of the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits), and highlighted the importance of this information, in light of the public data being used; and to enable NHS Digital to comply with its requirement to establish a legal basis for continuing the dissemination, and fulfil NHS Digital's public disclosure requirements. IGARD therefore asked that section 5(d) (iii) was updated with brief, specific yielded benefits, for example, by using the yielded benefits that were already outlined elsewhere in the application, such as, the use of data for acute care, analysis of referrals to outpatients and improving A&E policy. In addition, IGARD also asked that the yielded benefits provided, complied with NHS Digital's Data Access Request Service (DARS) Standard for Benefits. IGARD queried the reference in section 5(d) to *"policy profession"*, and asked that for clarity, a further explanation was added, confirming what was meant by this, for example, was this a Civil Service sub-profession. IGARD noted the statement in section 5(b) (Processing Activities) *"Following completion of the analysis the record level data will be securely destroyed.",* and were advised by NHS Digital that downloads within the DAE, were subject to the same policy as a usual dissemination of data by NHS Digital, in that, downloads were auditable, and NHS Digital had the authority to request audit of data destruction. IGARD noted the clarification from NHS Digital, and asked that section 5(b) was updated to make this explicitly clear. IGARD noted that, in respect of the privacy notice, section 4 (Privacy Notice) had not been adequately completed and NHS Digital were waiting for the applicant to clarify one of the following options; 1) *"In their opinion, their privacy notice complies fully with the ICO Guidance on individuals' right to be informed and/or";* 2) *"They have any intentions to update their privacy notice to comply with that guidance."*. IGARD asked that the applicant confirmed which of the undertakings they would be selecting. In addition, IGARD noted that it was their view that the applicant's privacy notice did **not** appear to fully comply with UK General Data Protection Regulation (GDPR) requirements, and suggested that this was reviewed. **Outcome:** recommendation to approve subject to the following condition: 1. To enable NHS Digital to comply with its requirement to establish a legal basis for continuing dissemination and fulfil NHS Digital's public disclosure requirements: a) To update section 5(d) (iii) with brief specific yielded benefits, for example, using the yielded benefits already outlined elsewhere in the application (such as: the use of data for acute care, analysis of referrals to outpatients and improving A&E policy) b) To ensure the yielded benefits comply with NHS Digital's DARS Standard for Benefits. The following amendments were requested: 1. To update section 5(b) to make clear that downloads are auditable within the DAE and NHS Digital have the authority to request audit of data destruction. 2. To add a further explanation to section 5(d) clarifying what is meant by *"policy profession"*, for example, is this a Civil Service sub-profession. 3. The applicant to confirm which of the undertakings they will be selecting in respect of the privacy notice (in section 4 of the application).

	The following advice was given: 1. IGARD noted that applicant's privacy notice did not appear to fully comply with UK GDPR requirements, and suggested that this was reviewed. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.3	University of Warwick: MR1376 - OHCAO (Out of Hospital Cardiac Arrest Outcomes) (Presenter: Dave Cronin) NIC-351810-N3G6N (v1.8) **Application:** This was a renewal and extension application for identifiable Medical Research Information Service (MRIS) List Cleaning Report; and an amendment to also receive identifiable Civil Registration and Demographics data. The purpose is for the OHCAO project, which is aiming to improve patient outcomes from out-of-hospital cardiac arrest (OHCA), which is a significant public health issue in the UK and a key priority for the NHS. Every year there are nearly 40,000 OHCAs where resuscitation is commenced or continued by paramedics, typically, less than 10% of OHCA patients survive to hospital discharge. To identify the key characteristics contributing to better outcomes in some ambulance services, reliable and reproducible systems are needed to be established for collecting data on OHCAs in the UK. NHS Digital advised IGARD that this Data Sharing Agreement had expired on the 25th January 2017. NHS Digital noted that section 3 (Datasets Held / Requested) incorrectly stated that the Demographics data would be disseminated *"bi-annually"*, and confirmed that this would need updating to accurately reflect this this would be disseminated on an annual basis. **Discussion:** IGARD noted this was an important study and welcomed the application. IGARD noted the update from NHS Digital in respect of the DSA expiring on the 25th January 2017, and also noticed that this was the 'start date' provided in the revised application provided for review; and advised NHS Digital that this should be amended to reflect a start date of 2021. In addition, IGARD also suggested that NHS Digital may wish to communicate with the applicant to confirm that there would be no sanctions imposed for holding the data whilst being out of agreement, and that any communication in respect of this should be uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD also noted and supported the update from NHS Digital, to amend section 3 to accurately reflect the Demographics data would be disseminated on an annual basis. IGARD queried the two Article 6 UK General Data Protection Regulation (GDPR) legal basis references in section 5(a) (Objective for Processing), particularly the one to *"Legitimate Interests"*, and were advised by NHS Digital that this was an error, and would need removing; IGARD noted and supported the update from NHS Digital to remove the incorrect reference to *"Legitimate Interests"* and the Article 6 UK GDPR legal basis. In addition, IGARD noted that an Article 9 UK GDPR legal basis had not been added to section 5(a), and asked that the appropriate legal basis was inserted as appropriate. IGARD queried the funding arrangements in place for the project, noting that no evidence of this had been provided as supporting documentation. IGARD asked that confirmation was provided that the funding was ongoing and sufficient; and that any additional funding documentation was uploaded to NHS Digital's Customer Relationship Management (CRM)

	system. In addition, IGARD also asked that section 5 (Purpose / Methods / Outputs) was updated to state that the funder would not have influence on the outcomes nor suppress any of the findings of the research. IGARD noted that section 1 (Abstract) referred to NHS Digital data being onwardly shared and were in agreement with NHS Digital's analysis that the data was sufficiently derived, however asked that this was updated to explicitly state that it was ***"derived"*** data that would be onwardly shared. IGARD noted the statement in section 5(b) (Processing Activities) *"…individuals **that** receive resuscitation for cardiac arrest…"*, and asked that this was amended to sensitively refer to *"…individuals **who** receive…"*. IGARD noted that the 'Annual OHCAO Epidemiology Report' referred to in section 5(c), that was for a 'wider audience', had a *"next publication date"* of December 2020; and asked that clarity was provided if this had now been published; and if so, that the application was updated accordingly to reflect this. IGARD also noted that the 'Annual Epidemiology Report for each individual Ambulance Service', that was referred to in section 5(c) (Specific Outputs Expected), was not *"published publicly"*, and asked that confirmation was provided if this could be published more widely; or if more appropriate, if extracts from the Report could be published. IGARD noted that within supporting document 2.1, the NHS Health Research Authority Research Ethics Committee letter, dated the 6th August 2013, specifically referred to a project; and asked that the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) were updated to reflect the project. IGARD queried the benefits outlined in section 5(d), and asked that this was updated to include the benefits accrued to patients and / or patient care; for example, in relation to the registry data. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the legal basis: a) To remove the reference to *"Legitimate Interests"* and the Article 6 UK GDPR legal basis in section 5(a). b) To insert an appropriate Article 9 UK GDPR legal basis in section 5(a). 2. To update section 1 to explicitly state that only *"**derived**"* data will ~~not~~ be onwardly shared. 3. To amend the reference in section 5(b) from *"…individuals **that** receive…"* to *"…individuals **who** receive…"*. 4. To clarify if the 'Annual OHCAO Epidemiology Report' as referred to in section 5(c) has been published, and if so, to update the application accordingly to reflect this. 5. To provide confirmation if the 'Annual Epidemiology Report for each individual Ambulance Service' as referred to in section 5(c) could be published more widely; or if more appropriate, if extracts from the Report could be published. 6. To update the yielded benefits in section 5(d) (iii) to reflect the project referred to in supporting document 2.1. 7. To update section 5(d) to include the benefits accrued to patients and / or patient care. 8. In respect of the funding: a) To confirm that the funding is ongoing and sufficient.

	b) To update section 5 to state that the funder will not have influence on the outcomes nor suppress any of the findings of the research. c) To upload any additional funding documentation to NHS Digital's CRM system.
2.4	<u>University of Sheffield: MR1452 - The Invasive Dentistry – Endocarditis Association (IDEA) Study: A study of the link between invasive dental procedures and critical medical events including infective endocarditis, myocardial infarction, stroke, pulmonary embolus and spontaneous pre-term birth. (Presenter: Denise Pine) NIC-116377-L5J9M (v1.7)</u> **Application:** This was an application to extend the existing Data Sharing Agreement (DSA) for identifiable Hospital Episodes Statistics (HES) and Medical Research Information Service (MRIS) data; and an amendment to 1) update section's 5(a), section 5(b) and section 5(c) to reflect the addition of a new research objective; and 2) to update section 5(d) (iii) to provide details as to why there are not yet any yielded benefits. The purpose is for a study that aims to investigate the link between invasive dental procedures and critical medical events, including infective endocarditis (IE), myocardial infarction, stroke, pulmonary embolus and spontaneous pre-term birth. Most concern has centred on IE, a heart infection with 30% first-year mortality where oral bacteria are the causal organism in 35-45% of cases. The study team will stratify IE patients into risk-groups based on previous inpatient medical care, which will enable them to, determine if there is an increased risk of IE following invasive dental procedures in individuals at high risk of IE, compared to individuals at lower risk for IE. **Discussion:** IGARD queried the reference in section 5(a) (Objective for Processing) to *"unnecessary prevention measures"* when referring to the safety of dental procedures and the expansion of the scope of the study; and asked that they were updated to ensure that it was clear that they were being undertaken globally or outside of the UK. IGARD noted that the application referred to "disease free survival". IGARD pointed out that a lay reader might not appreciate that "survival" in this context does not mean "not dying" but rather not experiencing any of the stated possible critical medical events following invasive dental procedures such as infective endocarditis, myocardial infarction, stroke, pulmonary embolus and spontaneous pre-term birth. IGARD noted that the reference throughout section 5(b) (Processing Activities) to *"HES IDs"*, and asked that this was either expanded to provide further clarity; or that a supportive explanation was provided for the acronym upon first use. IGARD noted the paragraph in section 5(b) that referred to *"Kaplan-Meier"* and asked that this public facing section be updated to ensure that this was written in a language suitable for a lay reader including, but not limited to, who or what "*Kap lan-Meie*r" was. IGARD noted the useful information within the study protocol, relating to patient and public involvement (PPI), and asked that section 5 (Purpose / Methods / Outputs) was updated to include a brief summary of this. IGARD queried whether the applicant would be receiving all the episodes of treatment that they were seeking to study, from the HES Admitted Patient Care Data (APC) flow of data since HES Outpatient and HES Critical Care may also contain valuable data. IGARD advised that they would be supportive of the applicant receiving any additional flows of data, for example critical care data, as may be necessary, to ensure the applicant was working with as full set of relevant data as possible.

	IGARD noted and applauded the applicant's approach taken in outlining the benefits in section 5(d) (Benefits) (including the style of language used when describing the benefits, for example, by not pre-judging the outcomes). **Outcome:** recommendation to approve The following amendments were requested: 1. To amend section 5(a) to ensure the reference to *"unnecessary prevention measures"* is clear that they are being undertaken globally or outside of the UK. 2. To update section 5(b) to either expand, or provide a supportive explanation for, the *"HES ID"* acronym upon first use. 3. To amend the paragraph in section 5(b) that refers to *"Kaplan-Meier"*, to ensure this is written in a language suitable for a lay reader. 4. To provide a brief summary of the PPI information in section 5, as outlined in the protocol. 5. To clarify the use of the term "survival" in this context for a lay reader. The following advice was given: 1. IGARD queried whether the applicant would be receiving all the episodes of treatment that they were seeking to study, from the APC flow of data; and advised that they would be supportive of the applicant receiving any additional flows of data, for example critical care data, as may be necessary, to ensure the applicant was working with as full set of relevant data as possible.
2.5	<u>Office for National Statistics (ONS): ONS Longitudinal Study (LS) (Presenter: Louise Dunn / Tracy Taylor) NIC-194340-D6F3B (v1.2)</u> **Application:** This was an amendment application to 1) Purpose 3 has been added to section 5(a), section 5(b) and section 5(c), for the Longitudinal Study (LS) / Census 2021 and Census Coverage Survey link; 2) a request to receive the full postcode of LS members for the LS / Census 2021 linkage work - justification for this field has been provided in section 5(b); 3) to add the following suite of documents to support this request: a) supporting document 3 - Legal basis of dataflows including data processor and data controller arrangements, b) supporting document 4 - Input/Output specification for the LS / Census 2021 linkage, c) supporting document 5 – LS / Census 2021 link dataflow diagram. The study has linked records at each census since the 1971 Census, for people born on one of four selected dates in a calendar year. These four dates were used to update the sample at the 1981, 1991, 2001 and 2011 Censuses. Life events data are also linked for LS members including births to sample mothers, deaths and cancer registrations. The latest update to the LS added data from life events that happened in 2017. The LS now holds data relating to approximately 1.2 million people. NHS Digital advised IGARD that although one of the amendments requested was to receive the full postcode of LS members, this information had not been reflected in section 3 (Datasets Held / Requested) of the application, and confirmed that section would be updated. **Discussion:** IGARD noted the update from NHS Digital, in respect of the full postcode request not being added in section 3 and supported the update to include in the data minimisation column of section 3. IGARD members noted the analysis undertaken by NHS Digital that the UK General Data Protection Regulation (UK GDPR) article 9 legal basis did not apply and were satisfied with the

	response. In addition IGARD noted that the applicant had their own statutory exception, and the common law duty of confidentiality did not apply. IGARD noted the reference in section 1 (Abstract) to ONS seeking ethical approval from the National Statistician's Data Ethics Advisory Board, and asked that if ethical approval had been provided for the Longitudinal Study, that written evidence was provided to NHS Digital; and that this was also uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD suggested that if the Advisory Board had not yet discussed the ethical support for the Longitudinal Study, that NHS Digital confirm with the applicant that this was on the next Advisory Board's meeting agenda, scheduled for the 17th February 2021; and if this item was not on the agenda, that confirmation was provided by the applicant that this would be on the next available agenda slot. In addition, IGARD also asked that a special condition was inserted in section 6 (Special Conditions) that the applicant must furnish to NHS Digital, written evidence of the provision of the Advisory Board's ethical support for the Longitudinal Study; and that this would also be uploaded to NHS Digital's CRM system. IGARD noted the statement in section 1 and section 5 (Purpose / Methods / Outputs) *"…members **that** have since died…"*, and asked that this was amended to sensitively refer to *"…members **who** have since died …".* IGARD queried the statement in section 5(a) (Objective for Processing) *"BIL 3,2,2 or BIL 4,2,2 by aggregation"* when referring to ONS's Secure Research Service (SRS) being Pan Government Accredited; and asked that the reference to *"BIL"* and the various numbers stated were either removed, or replaced with a brief lay summary. IGARD noted the reference in section 5(b) (Processing Activities) to the *"MIDAS"* database, and asked that a brief explanation was included with this reference outlining what the database was, as this was not clear. IGARD queried the information in section 5(b) that stated the five User Support Officers, who work for University College London, had all been supplied with *"ONS laptops"*; and asked that this was updated, to also include a clear statement, that this had been assured and was appropriate and secure. IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and queried if this was correct, for example, back-up or disaster recovery; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) if appropriate. IGARD noted that the applicant has undertaken to furnish a UK GDPR compliant privacy notice, and reiterated previous advice that it would aid transparency if the flow of data to NHS Digital was also noted in the privacy notice. IGARD advised that they would wish to review this application when it comes up for renewal or extension, due to the significant amount of data flowing and the national importance of the processing; and that this application would not be suitable for NHS Digital's SIRO Precedent route. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the National Statistician's Data Ethics Advisory Board:

	a) To provide written evidence of the provision of the Advisory Board's ethical support for the Longitudinal Study to NHS Digital. b) To upload the written evidence to NHS Digital's CRM system. c) To insert a special condition in section 6 that the applicant must furnish to NHS Digital written evidence of the provision of the Advisory Board's ethical support for the Longitudinal Study; and that this will be uploaded to NHS Digital's CRM system. 2. To update the data minimisation column in section 3 to reflect the full postcode has been requested. 3. To update the references in section 1 and section 5 from *"..members that…"* to *"…members **who**…"*. 4. To add a brief explanation of the MIDAS database in section 5(b). 5. To clarify if there are any additional storage locations and to amend section 2(b) if appropriate, for example back-up or disaster recovery. 6. To remove the references to *"BIL"* in section 5(a) and the various numbers stated, or to replace with a brief lay summary. 7. To update the *"ONS laptops"* reference in section 5(b), to also include a clear statement that this has been assured and is appropriate and secure. The following advice was given: 1. IGARD noted that the applicant has undertaken to furnish a UK GDPR compliant privacy notice, and reiterated previous advice that it would aid transparency if the flow of data to NHS Digital was also noted in the privacy notice. 2. IGARD suggested that NHS Digital confirm with the applicant that the Longitudinal Study is on the National Statistician's Data Ethics Advisory Board meeting agenda scheduled for the 17th February 2021; and if not, to ask for confirmation that this will be on the next available agenda slot. 3. IGARD advised that they would wish to review this application when it comes up for renewal or extension, due to the significant amount of data flowing and the national importance of the processing. 4. IGARD suggested that this application would not be suitable for NHS Digital's SIRO Precedent route.
2.6	<u>Ipsos MORI: CQC Adult Inpatient Survey Bespoke HES Extraction (Presenter: Kimberley Watson) NIC-407121-Z8K8K (v0.3)</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES) data Admitted Patient Care (APC) data, for a sample of 180,000 individuals who have had their latest spell in hospital between the 1st April 2020 and 30th November 2020. Ipsos MORI is the Co-ordination Centre for Mixed Methods for the NHS Patient Survey Programme. These surveys are run on either a yearly or two-yearly basis, across all NHS Trusts in England, and are mandated by the Care Quality Commission (CQC). The NHS Patient Survey Programme includes 5 surveys: 1) Adult Inpatients, 2) Maternity, 3) Children and Young People, 4) Urgent & Emergency Care and 5) Community Mental Health. Ipsos MORI, on behalf of CQC, would like to adopt a more centralised approach to their data collection for surveys aiming to use the CQC inpatient survey as a litmus test. Centralisation of identification of the cohort with NHS Digital collecting data for the sample, which will reduce the burden on Trusts. **Discussion:** IGARD queried the statements within the application, in relation to Ipsos MORI making decisions, for example, *"Ipsos MORI sets the survey criteria"*, *"Ipsos MORI wish to*

	utilise NHS Digital...", *"If this works, "Ipsos MORI will consider...[using this method for the other surveys]"*. NHS Digital noted that Ipsos MORI work under the direction of the CQC and had submitted the application on their behalf, and that CQC have final sign off of all criteria as part of their regulatory role. IGARD asked that the application was updated throughout to reword such references and to reflect the facts as advised in the verbal introduction. In addition, IGARD also asked that there was consistent narrative throughout that CQC would be making any final decisions on the use and processing design of the data, as per their regulatory role. IGARD noted the sample size of 180,000 individuals that were being used within the survey, and queried if the applicant had considered doing this comparison exercise with a smaller run of data. NHS Digital noted that the sample is based on 1,250 records rather than a random sample, comparison at trust level requires comparing against the same sample size to ensure consistency and national comparisons require results across all trusts. IGARD asked that section 5(a) (Objective for Processing) was updated, to specifically address the size of the sample, in particular, explaining why a smaller sample of Trusts, for example, 50% of Trusts would not suffice; and further clarity as to why **all** Trusts needed to be covered in this exercise. IGARD noted the information provided in supporting document 1, the 'NHS Adult Inpatient Survey 2020 Sampling Handbook' (page 11) that provided a further explanation as to why this exercise was being undertaken, and asked that some of this was replicated in section 5(a) for further transparency and since it was particularly helpful text. IGARD queried the objective for processing outlined in section 5(a) since it appeared to suggest that there may be scope to use the data for contacting patients, and asked that this was updated to clearly state that in carrying out the processing, the data would **not** be used for contacting patients. In addition, IGARD asked for further narrative as to why non identifiable data was flowing, as this was not clear within section 5 when referring to the sampling errors. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated that the application was not commercial, however asked that for transparency, this was updated, to note that Ipsos MORI was a commercial company charging a fee for its services on this pilot, and that if this pilot was successful, it would be rolled out more widely which would generate further fees on a wider scale for Ipsos MORI. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the application throughout to reword any refences to Ipsos MORI making decisions (please see the published minutes for further examples) and to ensure that there is a consistent narrative throughout that CQC will be making final decisions on the use and processing design of the data. 2. In respect of the size of the sample: a) To update section 5(a) to specifically address the size of the sample; in particular, explaining why a smaller sample of Trusts, for example, 50% of Trusts would not suffice. b) To clarify why all Trusts need to be covered in this exercise. c) To replicate some of the information in section 11 of the 'Sampling Handbook' (supporting document 1), in section 5(a) to further explain why this exercise is being undertaken.

	3. To update the beginning of section 5(a) to clearly state that in carrying out the processing, the data will not be used for contacting patients, and why non identifiable data is flowing. 4. To update section 5(e) to note that Ipsos MORI are a commercial company charging a fee for its services on this pilot and if this pilot is successful, it will be rolled out more widely which will generate further fees on a wider scale for Ipsos MORI.
3	Returning Applications IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-164594-K4C5N University College London (UCL) • NIC-389320-R4M6Z University of Nottingham • NIC-389134-S8L1C University of Oxford IGARD welcomed the three 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	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 9th February 2021 can be found attached to these minutes as Appendix B.
5 **5.1**	AOB: COPI Notice Extension IGARD noted that NHS Digital had received confirmation from the Secretary of State for Health and Social Care, that The Health Service Control of Patient Information (COPI) Regulations 2002 had been extended until the 30th September 2021. There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 05/02/21

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-360432-Z1Q8K	Group Application (NHS Birmingham and Solihull CCG, Birmingham City Council, and Solihull Metropolitan Borough Council)	19/11/2020	1. In respect of deferral point 1: a) To provide written confirmation that NHS Digital's PTE Directorate is content with the proposed legal basis; b) To ensure that the written confirmation from PTE is uploaded to NHS Digital's CRM system. 2. In respect of the NDO: a) To update section 5 to clearly explain the approach of the NDO; b) To provide an updated supporting document 3 (if available) to clarify the current approach in respect of the NDO. 3. In respect of direct care: a) To update the contradictory information within section 5(a); b) To update section 5(a) to ensure that it clearly states that individuals can only be linked, on a case by case basis, in exceptional circumstances and for the specific purpose of direct care; c) To provide a specific example or examples of when data may be linked in exceptional circumstances and for the specific purpose of direct care.	IGARD members	Quorum of IGARD members	IGARD Comments: The examples are **not** clearly setting out exceptional circumstances where identification is needed for direct care in section 5. This could be addressed by rewording, but it needs to reflect what the data recipients will be doing and aligned with the requirements of the NDO for example. The key point to make re re-ID is that this is only done at the instigation of the particular GP practice. The medicines example could stand a re-write eg: *Practices can re-ID a list of patients with a high number of medications (ingredient count) and review the medication for these patients. This can help address the risk of polypharmacy which is recognised as an adverse risk factor for patient safety.*

						A by-product of such reviews may be to reduce costs of medication.
NIC-182098-Y4H0W	University of Cambridge	26/11/2020	1. In respect of the data controllership: a) To provide a written explanation (in terms of the GDPR and NHS Digital's DARS Standard on Data Controllers) why the University of Oxford and the Cambridge University NHS Foundation Trust were **not** considered joint Data Controllers, in light of the information provided in the supporting documents. b) If the University of Oxford and/or the Cambridge University NHS Foundation Trust are considered joint Data Controllers, to update the application throughout to reflect this. 2. In respect of REC approval: a) To provide confirmation that **all** the versions of the consent materials have been approved by REC. b) To provide confirmation that there are no other versions of the consent materials available, that have not been provided to NHS Digital. c) To upload a copy of the ethics approval to NHS Digital's CRM system.	IGARD members	Quorum of IGARD members	IGARD confirmed the conditions have been met (and in the case of 1 b no longer relevant). Further information from the HRA with regard to sponsors are data controllers guidance can be found here.
NIC-284866-L7K4D	University of Sheffield	17/12/2020	1. In respect of HRA CAG support: a) To confirm that the patient notification strategy report that was due in October 2020 has been shared with HRA CAG. b) To provide written confirmation that HRA CAG have confirmed that the condition relating to this report has been met. c) Noting sex is not an identifier in its own right and does not require HRA CAG	IGARD members	Quorum of IGARD members	Comments from the IGARD Chair: *"Section 5e (Is the Purpose of this Application in Anyway Commercial?) is currently answered 'no'. The topic of potential commercial exploitation is covered in 5c, but it may be advisable to change 5e to 'yes'."*

			approval, IGARD asked that the applicant make HRA CAG aware of the change in the data going to NHS Digital (changing name for sex). 2. To provide further details of any potential commercial exploitation now or in the future, and if it does have a commercial element, to address the points required by the NHS Digital DARS Commercial Standard within the application. 3. To provide further clarification of the YAS linkage to "regional hospital data", how this will take place and the legal basis to undertake this.			
NIC-348357-W0P1W	Group Application (NHS Devon CCG, NHS Kernow CCG, Cornwall Council)	19/11/2020	1. In respect of direct care: a) To update the contradictory information within section 5(a); b) To update section 5(a) to ensure that it clearly states that individuals can only be linked, on a case by case basis, in exceptional circumstances and for the specific purpose of direct care; c) To provide a specific example or examples of when data may be linked in exceptional circumstances and for the specific purpose of direct care. 2. In respect of Cornwall Council: a) To provide a justification within section 5 as to why the Council require access to the Devon data (f not forming an ICS); or b) To clarify in section 5 of any future plans to become an ICS, to justify the need for Devon data by the Council.	IGARD members	Quorum of IGARD members	Comments from the IGARD Chair: *I am content that the outstanding conditions 1b and 1c* have been met **if** additional wording to fully address 1c is added in the body of the application, for example:* *"Practices can re-ID a list of patients with a high number of medications (ingredient count) and review the medication for these patients. This can help address the risk of polypharmacy which is recognised as an adverse risk factor for patient safety. A by-product of such reviews may be to reduce costs of medication."*

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:

- NIC-186881-Z9P9B NHS Berkshire West CCG

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, 9th February 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Geoff Schrecker (IGARD Specialist GP Member)
In attendance (NHS Digital):	Dan Goodwin (DARS)
	James Gray (DARS)
	Karen Myers (IGARD Secretariat)
	Aneesah Shahpal (DARS – observer)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual 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[1] **Background:** This was a business as usual (BAU) application 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 rest of the application remains unchanged and is the templated GP Data for Pandemic Planning & Research (GDPPR) CCG pseudo template application. **IGARD Observations:**

[1] 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

	IGARD members noted the update from NHS Digital and that the application was to be presented to the Profession Advisory Group (PAG) on Wednesday, 10th February and IGARD business as usual (BAU) meeting on Thursday, 18th February 2021. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update. **Significant risk areas:** • Type 1 objections are applied to the GDPPR dataset. Accordingly, use of GDPPR data for direct care (i) is inconsistent with assurances provided to the patient when they initiated their type 1 objection and (ii) could disadvantage those patients who have a type 1 objection. • Lack of transparency for those patients who have type 1 objections applied to their data and how patients would be made aware of the processing of their data for this purpose. • Clear justification in section 5 outlining how the GDPPR data will support the new purpose
2.2	<u>NIC-433257-K6Q2Y University of Edinburgh: HEAL-COVID</u> **Background:** This was a request by NHS Digital to provide an early review of the '*HEAL-COVID Adult Participation Information Sheet* v0.7_05022021*' and the '*HEAL-COVID website data processing statement draft v0.2*'. *(PIS) HEAL-COVID is a platform trial comparing treatments for the long term consequences of COVID-19. Patients who are about to be discharged from hospital, having been admitted with COVID-19, will be asked to take part in the trial for 12 months. This was a National Institute for Health Research (NIHR) urgent public trial. The University of Cambridge and Cambridge University Hospitals NHS Foundation Trust jointly sponsor the trial, with the day to day running of the study carried out by a team based at the Liverpool Clinical Trials Centre and researchers at the University of Cambridge. The following observations were made on the basis of the two documents provided only. **IGARD Observations:** IGARD noted that the applicant on the NHS Digital customer relationship management (CRM) system was the University of Edinburgh, however the documentation provided clearly indicated that this was not the case. NHS Digital noted that CRM would be updated to clearly identify the correct applicant. The other parties mentioned would need to be assessed on the facts as to whether they fulfilled the definition of Data Controller or Data Processor (as per NHS Digital's Standard). With reference to the '*HEAL-COVID Adult Participation Information Sheet v0.7_05022021*', IGARD made the following high level comments and suggestions, on the assumption that the clinical trial involved only adults who are defined as being 18 years or older: • With reference to point 4 (consent form): o To remove reference to "*medical*" in relation to the data held by NHS Digital • With reference to point 5 (consent form):

	○ To remove reference to "…*clinically important research questions*" and replace with "…*research purposes*" • With reference to point 10 (consent form: which is an optional question to answer) ○ To clearly articulate, as per '*HEAL-COVID website data processing statement draft v0.2*' that data may be sent "abroad" (as well as the UK) and that "*companies*" (as well as NHS and universities) may also be involved. ○ To break down point 10 to be more granular to how a patient's data may be used, such as "*UK*", "*aboard*", "*NHS Organisations*" etc • With reference to point 11 (consent form: which is an optional question to answer): ○ To consider whether the applicant wished to capture the participant's postal address, in addition to the telephone number and / or email • To insert explanatory narrative in the body text of the PIS that clarifies that identifiers will be flowing to NHS Digital. • To expand the narrative under the title "*information sharing for other research*" to capture further details from the '*HEAL-COVID website data processing statement draft v0.2*' • With reference to the applicant wishing to follow up for "*12 month*s": ○ IGARD suggested that the applicant may wish to consider their "*12 months*" timeframe and update the narrative to state that the project is currently planned for 12 months but may be extended to ensure that the consent materials did not limit any future research, including linkage or extended follow up ○ IGARD suggested that the applicant may also wish to receive and link retrospective data, for example to check a cohort member's self-reported medical history. If there is any possibility of this in the future, this could also be outlined in the PIS. ○ To be clear on the date from which the applicant would follow cohort members since it was not clear if this was from the trial start date, or when the cohort member signed the consent form • IGARD suggested that the narrative within the PIS should be updated to reflect that data would be requested for the participant's "*lifespan and beyond*" or some other such form of words to make clear that the applicant would be wanting to ascertain cause, date and location of death. • With regard to capacity to sign the consent form: ○ IGARD suggested that the applicant may wish to review the latest Health Research Authority (HRA) guidance with regard to capacity and consent. ○ IGARD suggested that the signature box on the consent form "*to be completed by the personal or professional legal representative if the participant does not have capacity*" be updated to clearly reflect in what capacity the signatory is signing (personal representative **or** legal representative) ○ As the participant may have been discharged from hospital with persistent incapacity, to reconsider the wording which currently appears to contemplate temporary incapacity only.
2.3	<u>NIC-411161-G4K7X University of Oxford: PRINCIPLE Trial</u> **Background:** This was a verbal update following previous discussions at the COVID-19 response meetings on the 27th October and 10th November, to add GP data from NHS Digital

	to the application (not supplied) in addition to the Pillar 2 data and SCR access already approved under their current application. The team require the GP data in order to follow up patients for 28 days and advice is sought as to whether this additional flow would be covered appropriately under the already approved application. The following observations were made on the basis of the verbal update only. IGARD did not receive a copy of application v1.2 or supporting documents. **IGARD Observations:** IGARD members noted the update from NHS Digital and that the application was to be presented to the Profession Advisory Group (PAG) on Wednesday, 10th February and IGARD business as usual (BAU) Meeting on a date yet to be confirmed. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update. **Significant risk areas:** • Justification for the requirement of the GP Data for Pandemic Planning & Research (GDPPR) data, since other NHS Digital data such as Hospital Episode Statistics Admitted Patient Care (HES APC) and Intensive Care National Audit & Research Centre (ICNARC) data appeared to provide a greater number of relevant additional data fields that may be useful. Consideration of asking for those datasets (for example ICNARC) as an alternative, or in addition to GDPPR. • To clearly show how the GDPPR data has been minimised to code blocks / sets, in line with NHS Digital's Data Minimisation Standard
2.4	<u>TACKLE (No NIC number)</u> **Background:** This was a request by NHS Digital to provide an early view on the proposed method of recruitment for a clinical trial and document '*TACKLE study recruitment.pptx*'. NHS Digital are seeking a view on the possibility of using the Covid-19 UK Non-hospital Antigen Testing Results (Pillar 2) data to support the clinical trial. NHS Digital also noted that they were seeking further advice from NHS Digital's Privacy, Transparency and Ethics Directorate (formerly Information Governance) and NHS Digital's prioritisation front door. The following observations were made on the basis of the PowerPoint presentation document only. **IGARD Observations:** IGARD members noted the verbal update from NHS Digital and that the NHS Digital contact centre would be contacting those people who had had a confirmed SARS-CoV-2 infection and/or early onset of symptoms to recruitment them to the TACKLE trial using the Pillar 2 data and were broadly supportive of the clinical trial (based on the presentation and verbal update provided by NHS Digital). IGARD members noted that the Testing for Coronavirus privacy information seemed to cover the use of the data for this purpose "*If you test positive or negative, you may also be contacted by DHSC to see if you wish to contribute to the research effort of COVID-19. If you are*

	interested in doing this, you need to follow the link in the text message." In addition "*Your information may also be used for different purposes that are not directly related to your health and care. Wherever possible, this will be done using information that does not identify you (anonymous data).*" and were satisfied that the privacy notice did provide adequate information. IGARD, reiterated previous concerns in relation to the use of such databases and ensure citizens were not inundated with requests to be part of a trial, and how those contacted could opt out of being contacted again in future (beyond exercising a national data opt-out). Separate to this application, IGARD members urged NHS Digital to take on a wider piece of work looking at the clinical trials and use of Permission to Contact database and databases such as Pillar 2 to ensure appropriate transparency and that contacting citizens did not become overly intrusive. It appeared that COVID-19 testing may become even more frequent for citizens as the pandemic develops and more variants appeared, and consideration should be given to an express opt in permission when requesting a COVID-19 test.
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.