Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 29 October 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. 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:**
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Vicky Byrne-Watts	Data Access Request Service (DARS)
James Gray	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 2.1 – 2.4)
Denise Pine	Data Access Request Service (DARS)
Andy Rees	Data Access Request Service (DARS)
Bethan Thomas	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 22nd October 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.

	Out of committee recommendations: An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	<u>University of Edinburgh: UK Prospective Diabetes Study (UKPDS) Legacy Study: long-term follow up of participants into electronic health records (Presenter: Kimberley Watson) NIC-265261-W7P8W</u> **Application:** This was a new application from the University of Oxford for Hospital Episode Statistics (HES), Civil Registrations (CR) and Emergency Care Data Set (ECDS), for the purpose of linking participants in the UK Prospective Diabetes Study (UKPDS) trial to all death and hospitalisation health records in order to measure the effect of the treatments in this study on death, major medical illnesses, and costs of treatment. The UKPDS was a randomised, multi-centre trial of glucose-lowering and antihypertensive therapies in 5,102 patients with newly diagnosed type 2 diabetes that ran in 23 clinical centres for twenty years from 1977 to 1997. The UKPDS trial investigators would now like to evaluate the effects of the randomised treatments on dementia and other measures of long-term health. **Discussion:** IGARD noted that the applicant was listed on the application as the 'University of Edinburgh', however this was a University of Oxford application, with the primary investigator holding a "…*substantial contract*…" with both the University of Edinburgh and University of Oxford. IGARD suggested that the applicant give further clarification with regard to the use of the word *"substantial"*, or to amend as may be necessary. In addition, NHS Digital should give thought to amending the application title to correctly show the applicant organisation. In addition, noting that the Nuffield Department for Public Health (NDPH) was listed as a Data Processor in section 1(c) (Data Processor(s)), IGARD asked that this section be updated to correctly list the University of Oxford (the legal entity) as the Data Processor and to subsequently list the NDPH as the location address. Noting that the original study ended in 1997, IGARD queried the legal basis for the University of Oxford to hold identifiers from the time of the original study until the Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support was in place. IGARD asked that a copy of the original consent materials were provided, which were consistent with the applicant holding identifiable data from the end of the study period until obtaining s251. If the original consent materials were **not** consistent with the identifiers being held from the study period ending in 1997 to obtaining s251, IGARD suggested that NHS Digital request that the applicant inform both HRA CAG and the relevant Research Ethics Committee (REC), and that written acknowledgement of this fact be received from both. If the applicant was unable to locate a copy of the original consent materials, IGARD suggested that the applicant confirm that both HRA CAG and REC had been informed that they had held data on an indeterminate basis from the end of the study period in 1997 until s251 support was obtained, and that this acknowledgement of fact be provided in writing. In addition, IGARD asked that all relevant supporting documentation be uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD suggested that consent forms may be held in a patient's medical records. Noting the Scottish ethical approval in place, IGARD suggested that a copy be provided, and uploaded to NHS Digital's CRM system.

	IGARD suggested that the reference to "…*the data from NHS Digital is not considered confidential*…" be removed, since it was not accurate. IGARD noted a discrepancy between the cohort figures in section 3 (Datasets Held / Requested) and HRA CAG documents provided as part of the review, and suggested that the application be updated throughout to ensure consistency with supporting documentation. In addition, and noting NHS Digital's DARS Standard for Data Minimisation, IGARD asked for clarification in section 3 as to whether it was possible to further minimise the data within HES. Noting the datasets requested in section 3(b) (Additional Data Access Requested), IGARD suggested that the applicant may wish to consider also requesting Mental Health Minimum Data Set (MHMDS) as an additional dataset, in order to further identify cohort members diagnosed with dementia. IGARD noted that HES may not be sufficient to pick up dementia and would be supportive of this additional request for data. IGARD suggested that section 5(a) (Objective for Processing) 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 in section 5b (Processing Activities) that the applicant wished to retain identifiers for linkage for "…*up to a year*…", and asked that a clear explanation be given for this rationale. In addition, IGARD asked that it be clearly set out in section 5(b) what physical protections were in place to segregate the data, such as by use of role or task-based access controls, since it was not clear. Noting that the outputs from this valuable study had been in use for a number of decades, IGARD strongly suggested that the applicant populate section 5(d)(iii) (Yielded benefits) with some of the valuable outputs generated by the original study. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the consent material: a. To produce a copy of the original consent materials which are consistent with the applicant holding data from the end of the study period to the time of obtaining s251 support, or b. To produce a copy of the original consent materials which may show that identifiers could not be held from the end of the study period to obtaining s251 support but that both HRA CAG and the REC have been informed and have acknowledged this fact in writing, or c. If no consent materials can be located, to confirm that both HRA CAG and the REC have been informed that they had held data on an indeterminate basis from the end of the study period until s251 support obtained and they have acknowledged this fact in writing; and d. To upload all relevant additional documentation to NHS Digital's CRM system. The following amendments were requested: 1. To update section 1 to remove reference to "…*the data from NHS Digital is not considered confidential*…". 2. In respect of section 1(c): a. To add in the University of Oxford as the Data Processor (the legal entity). b. To remove reference to the NDPH as the named Data Processor and instead specify NDPH as a location.

	3. To amend the application throughout to ensure that the cohort sizes referred to within this application are consistent with the supporting documentation. 4. To ensure that where appropriate the term *"gender"* is replaced with the term *"sex"* to reflect the available field in the data set requested. 5. To clarify in section 3 whether it is possible to further minimise the data within HES (in line with NHS Digital's DARS Standard for Data Minimisation). 6. To clearly explain in section 5(b) why identifiers will need to be retained for linkage "…*up to a year*…". 7. To set out in section 5 what physical protections are in place to segregate data, such as by use of role or task based access controls. 8. To confirm in section 5(a) the meaning of "…*the primary investigator holds a* ***substantial*** *contract*." or amend as may be necessary. 9. In respect of the ethical approval: a. To provide a copy of Scottish ethics approval which is in place. b. To upload a copy of the ethics approval to NHS Digital's CRM system. The following advice was given: 1. IGARD strongly suggested that the applicant populate section 5(d)(iii) with some of the valuable outputs generated by the original study. 2. IGARD suggested that the applicant may wish to consider also requesting MHMDS data, as an additional dataset, to identify cohort members diagnosed with dementia. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.2	<u>University College London: Evaluating variation in special educational needs provision for children with Down syndrome and associations with emergency use of hospital care. (Presenter: Kimberley Watson) NIC-50975-X6N3J</u> **Application:** This was an extension application to extend the term of the agreement until 2023; and an amendment to 1) to add the Office for National Statistics as a Data Processor, and 2) to allow the linkage of the National Congenital Anomalies and Rare Diseases Registration Service-Hospital Episode Statistics (NDSCR-HES) data for the study cohort to the National Pupil Dataset (NPD) held by the Department for Education (DfE), by utilising a subset of data from an existing agreement (NIC-381972-Q5F0V). NIC-381972-Q5F0V covers a dataset of all children and young people born from 1 September 1995 and appearing in HES records. An objective of NIC-381972- Q5F0V is to analyse and compare health, education and social care outcomes for vulnerable and non-vulnerable children and young people before, during and post-COVID-19. The study is looking at variation across England in health, social care and education services for children with Down Syndrome and determining the impact on emergency use of hospital care. NHS Digital noted that in section 3 (Datasets Held / Requested) no new additional data was being requested under this application. **Discussion:** IGARD noted that this was a very useful study and supported the research being undertaken. IGARD noted the update from NHS Digital that no new data was flowing under this application and were content that the various underlying Data Sharing Agreements (DSA) relied upon for the flow of data were not relying on the Health Service Control of Patients Information (COPI) Regulations 2002.

	It was not clear to IGARD if the National Data Opt-outs (NDOs) had been applied at each stage where s251 support was being relied upon for the legal basis, and asked that further clarification was sought. If NDOs had not been applied at each stage, an explanation should be provided within the application. IGARD suggested that NHS Digital may wish to seek advice from the NHS Digital Caldicott Guardian and / or Information Governance (IG) Directorate or discuss with the Health Research Authority Confidentiality Advisory Group (HRA CAG) on this point. Noting that only page 1 of the now lapsed original funding agreement had been provided as a supporting document, IGARD asked that a copy of the new National Institute for Health Research (NIHR) funding agreement be provided and uploaded to NHS Digital's Customer Relationship Management (CRM) system. In addition, and noting that public and patient involvement (PPI) was a key requirement of being a NIHR funded study, IGARD suggested that section 5 (Purpose / Methods / Outputs) be updated throughout to ensure that all relevant PPI was explained, noting the dissemination work to key groups. IGARD noted the territory of use as *"England and Wales"*, however the IT provider was based in Belfast, Northern Ireland and asked that section 2(c) (Territory of Use) was updated to confirm that they were not handling any of the data under this application. IGARD noted in section 5a (Objective for processing) that "…*PHE has section 251 support to collect information on cases of CARDs* in England*…" however it was not clear to IGARD what was meant by the term "*cases*" and asked for clarification as to whether this was referring to *"people"* or *"entries on a register"*. *congenital anomaly or rare disease. IGARD noted the reference to "…*the main findings so far allude to the quality of the data linkages rather than the expected benefits*…" in section 5(d) (iii) (Yielded Benefits) and asked that this be updated to confirm that there was a benefit to look at the quality of data linkages. **Outcome:** recommendation to approval subject to the following condition 1. In respect of the National Data Opt-outs: a. To clarify whether NDOs have been applied at each stage where s251 support has been relied upon, or b. If NDOs have not been applied, to explain why not. The following amendments were requested: 1. To update section 2(c) to confirm that the IT provider based in Belfast is not handling the data. 2. To clarify in section 5(a) "…*to collect information on cases*…" and if "*cases*" is referring to "people" or "entries on a register". 3. To update the reference to "*linkage*" in section 5(d)(iii) to confirm that there is a benefit to look at the quality of data linkage. 4. To ensure all relevant PPI is explained in s5, particularly any PPI disclosed to the NIHR. 5. In respect of the NIHR funding: a. To provide a copy of the funding agreement, and b. To upload a copy of the funding agreement to NHS Digital's CRM system. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.

2.3	Barts and the London School of Medicine and Dentistry: Genes and Health (Presenter: Kimberley Watson / Vicky Byrne-Watts) NIC-338864-B3Z3J **Application:** This was a new application for Hospital Episode Statistics (HES), Civil Registrations (CR) and Emergency Care Data Set (ECDS), Mental Health Minimum Data Set (MHMDS), National Diabetes Audit (NDA), Maternity Services Data Set (MSDS), Mental Health Services Data Set (MHSDS). The purpose is to develop and maintain a bioresource of genetic and health record data available to the research community to improve the health of British people with Pakistani and Bangladeshi heritage through high quality research. Health record data is a key requisite of this objective, as it is used to characterise in detail health and disease in study volunteers across their life course. **Discussion:** IGARD welcomed the application which came for advice on the consent materials and patient information leaflets (PIL), and without prejudice to any additional issues that may arise when the application is fully reviewed. The Acting Deputy Caldicott Guardian had been asked to proffer a view on the documentation provided and in particular if the consent materials were compatible with the proposed processing to satisfy the common law duty of confidentiality. The Acting Deputy Caldicott Guardian (ai) had reviewed the documentation and was in agreement with NHS Digital's assessment and IGARD's view that the consent materials were compatible and, along with IGARD, suggested improvements to future versions of the materials including, but not limited to, providing more concise and clear information and detailing the interaction with possible sub-licencing. In addition, IGARD suggested that any future newsletters included, amongst other things, detailed information about the proposed sub-licencing. IGARD suggested that NHS Digital may wish to work with the applicant to review previous sub-licencing Data Sharing Agreements (DSAs) already in place and in conjunction with the NHS Digital DARS Standard on sub-licencing. In addition, IGARD were supportive of the applicant requesting a 'list clean' to minimise the risk of causing distress by contacting the family of someone who was now deceased. Notwithstanding the suggested future amendments to the materials, IGARD suggested that the applicant's website be updated as soon as possible to remove reference to "*no personal details*" and use of the word "*anonymised*" and as a first step prior to the consent materials and PILs being updated. IGARD noted that the applicant may wish to review the Information Commissioner's Office (ICO)-funded publication on the General Data Protection Regulation (GDPR) and Genomic data: https://www.phgfoundation.org/documents/gdpr-and-genomic-data-report.pdf. In addition IGARD drew the applicant's attention to Schrems I v Screms II, and the EU-US privacy shield and the UK Government's published response to the European Court of Justice decision in the Schrems II case: https://www.gov.uk/government/news/uk-government-response-to-the-european-court-of-justice-decision-in-the-schrems-ii-case Noting that the application was still draft, IGARD members provided a number of observations to NHS Digital including, but not limited to, reference to "*anonymised data*", an explanation with regard to no linkage to identifiable data, reference to commercial in section 5(e) (Is the purpose of the application in anyway commercial) and "*no moral or ethical issues*".

	IGARD commended the applicant on the level of patient and public involvement (PPI) undertaken and the good networks involved in the study. **Outcome:** IGARD welcomed the application which came for advice on the consent materials and patient information leaflets and, without prejudice to any additional issues that may arise when the application is fully reviewed, made the following comments: 1. IGARD and the Acting Deputy Caldicott Guardian agreed with NHS Digital's assessment of the consent materials in that they were compatible with the proposed processing and would, on balance, satisfy the common law duty of confidentiality. Improvements for future versions of the materials were suggested. 2. Notwithstanding the above, IGARD suggested that the applicant update their website promptly to make improvements, including but not limited to, removing reference to "*no personal details*" and use of the word "*anonymised*". 3. IGARD noted that a future newsletter dissemination may be supported by a list clean and suggested a future iteration should include, amongst other things, detailed information about the proposed sub-licencing. 4. IGARD suggested that NHS Digital work with the applicant to review previous sub-licencing DSA's already in place, and in conjunction with the NHS Digital DARS Standard on Sub Licencing. 5. IGARD drew the applicant's attention to a recent ICO-funded publication on GDPR and Genomic Data. 6. IGARD noted that the application was still in draft and provided a number of observations.
2.4	<u>The Nuffield Trust for Research And Policy Studies In Health Services: Prisoner health: Understanding prisoners' healthcare needs, their use of healthcare services and quality of care received (Presenter: Denise Pine) NIC-195377-M9L8Z</u> **Application:** This was a renewal and extension application for pseudonymised Hospital Episode Statistics (HES) data; and an amendment to 1) amend the purpose of the Data Sharing Agreement (DSA) to extend the first phase of the work over a longer time period, 2) to amend the methodology to be used in phase 2. The purpose of the study is to understand prisoners' healthcare needs, their use of healthcare services and quality of care received. Ultimately, the research aims to use routine hospital data to better understand the healthcare needs of prisoners, their use of hospital services and how the quality of care for prisoners compares to the non-prisoner population. NHS Digital noted that the bridging file dataset had not been included in section 3(b) (Additional Data Access Requested). **Discussion:** IGARD noted the update from NHS Digital and asked that section 3(b) be updated to include reference to the bridging file. IGARD reiterated their previous comments made when presented at the 5th July and 26th July 2018 IGARD meetings, that the study was using the prison postcode as a proxy to identify patients in the penal establishment, however for those prisons located in residential areas or for those living on the prison site suggested that section 5 (Purpose / Methods / Outputs) of the application be updated to clearly state that the prison postcode would '**usually**' include only the prison population and not those working in the prison or residential properties in close proximity. In addition, further clarification should be provided in section 5 as to the checks undertaken to validate the use of prison postcodes.

	IGARD had previously queried how the control group was being derived, and NHS Digital confirmed there was no specific control group created, however it was still unclear within the application, and IGARD suggested that section 5 of the application be updated to include a clear statement that no specific control group was created for this study, and that the matched patient group would come from the applicant's underlying Data Sharing Agreement (DSA). IGARD noted in section 5(b) (Processing Activities) reference to "…*the Nuffield Trust intends to feedback to NHS Digital in a meaningful way on whether the initial postcode approach fails at a secondary control*…" and suggested this was updated to clarify how the applicant had reported back to NHS Digital. IGARD reiterated their previous point that the prison population would be limited to how they access information relating to this study and suggested that a clear statement be included in section 4 (Privacy Notice) of the fair processing undertaken by the applicant to ensure the prison population had access to the study and information. IGARD noted that "…*The Nuffield Trust will work with an expert panel supporting the project to identify key clinical outcomes amenable to identification in hospital data which will provide useful information regarding unmet need*…" and although IGARD noted the wide range of people on the expert panel, asked that section 5(a) (Objective for Processing) be updated to describe that the expert panel is advisory and would not be providing a formal governance role, if that in fact was their role. IGARD noted reference to the "*Anonymisation Code of Practice*" in section 1 (Abstract) and suggested that it be removed and replaced with the agreed standard wording. IGARD noted that section 1 should be updated to accurately describe the legitimate interest and that section 5(a) should be updated to ensure processing was clearly linked to the specific legitimate interests. IGARD noted in section 5(a) reference to "…*the data period will cover 2019/20*…" however it was not clear if this meant the financial year 2019/20 or 2019 and 2020, and suggested that since the applicant required data for both 2019 and 2020 that the application be updated throughout to confirm that HES data was required for both 2019 **and** 2020. IGARD noted technical jargon in section 5 and asked that it be clearly defined with a supportive explanation in a language suitable for a lay reader for technical jargon, such as *"'STARTAGE/ARRIVALAGE/APPTAGE of 7001 or 1"*. IGARD noted reference to publications in section 5(d)(iii) (Yielded Benefits) and suggested that these be removed and added to section 5(c) (Specific Outputs) **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the prison postcode: a. To clarify in section 5 that the prison postcode will 'usually' include only the prison population and not those working in the prison or residential properties in close proximity. b. To clarify what checks are made to validate the use of prison postcodes and include an explanation in section 5 of the measures undertaken. The following amendments were requested: 1. To update section 5 to describe the expert panel is providing advice and **not** providing a formal governance role, if that is their role.

	2. To update section 3(c) and section 1 to remove reference to the '*Anonymisation Code of Practice'*, and replace with the agreed revised wording. 3. In respect of the legitimate interest: a. To update section 5(a) to ensure reference to the specific Legitimate Interests as linked to the processing. b. To update section 1 to accurately describe the legitimate interest with the agreed standard wording. 4. To include within section 5 a clear statement that no specific control group was created for this study and that the matched patient group will come from the applicant's underlying separate DSA. 5. To update section 3(b) to include the bridging file. 6. To be clear throughout the application that the HES data is required for both 2019 **and** 2020 7. To update section 5(b) to clarify how the applicant has reported back to NHS Digital. 8. To update section 5(b) to ensure that technical jargon is defined or further explained upon first use, such as '*STARTAGE/ARRIVALAGE/APPTAGE of 7001 or 1*'. 9. To remove any specific outputs from section 5(d)(iii) and move to section 5(c). The following advice was given: 1. IGARD reiterated their previous point that the applicant should clearly state the steps undertaken to inform the prison population of the study and how they can access the information. It was agreed the condition would be approved out of committee (OOC) by IGARD Members
2.5	University Hospital Southampton NHS Foundation Trust: A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older (Presenter: James Gray / Andy Rees) NIC-409280-J6T3M **Application:** This was a new application for permission to utilise the COVID-19 Permission to Contact (CV19 PtC) dataset, for the purpose of recruiting participants into a vaccine trial. This is a multicentre, randomized, double-blind, placebo-controlled, Phase 3, pivotal efficacy and safety study in adults aged 18 and older. The efficacy, safety, and immunogenicity of Ad26.COV2.S will be evaluated in participants living in, or going to, locations with high risk for acquisition of SARS-CoV-2 infection after administration of 2 doses of study vaccine. The study will consist of a screening phase of up to 28 days, a 60-week double-blind study period (including the administration of 2 doses of study vaccine (1 dose on Day 1 and 1 dose on Day 57), after randomization), and a long-term follow-up period of 1 additional year. The duration of individual participation, including screening, will be maximum 2 years and 3 months. NHS Digital noted that ethics approval was not in place. NHS Digital noted reference to "*compound*" in section 5(e) (Is the purpose of the application in anyway Commercial) and that this would need to be updated to reference "*vaccine*". **Discussion:** IGARD noted the update from NHS Digital and that section 5(e) would be updated to correct the reference from "…*compound*…" to "….*vaccine*…", and in addition asked that this newly updated text be replicated in section 5(a) (Objective for Processing).

	In addition, section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) should be updated to explicitly state that this application was about vaccine trials, since it was not altogether clear. Noting that the target for recruitment was approximately 6,000 participants, IGARD asked that an estimate of the number of overall contacts required to achieve this figure be provided in section 5, since it would not be advantageous for one study to "use up" a disproportionate section of the database in order to obtain the relevant participation figures. In addition, IGARD suggested that section 5 be clear as to the pre-screening that could be undertaken by NHS Digital and to clearly quantify in terms of likely loss of potential cohort numbers from the pre-screening. IGARD noted reference in section 1 to "…*the data will be pseudonymised prior to dissemination by NHS Digital to the data recipient*…" and suggested that reference to 'pseudonymised data' flowing to the applicant be removed, since it was incorrect. Noting the information provided in section 3 (Datasets Held / Requested), IGARD noted that the common law duty of confidentiality was met due to the underlying consent. IGARD noted in section 5(a) that "…*The duration of the individual participation, including screening, will be maximum 2 years and 3 months*…" however observed that NHS Digital may wish to raise with the applicant that they could consider follow up over a longer period of time, since it was not clear of the long term outcomes for those suffering from *"long-COVID"*, for example. **Outcome:** recommendation to approve subject to a condition 1. In respect of the ethics approval: a. To provide a copy of the evidence that ethics approval is in place. b. To upload a copy of the ethics approval to NHS Digital's CRM system. The following amendments were requested: 1. To update section 1 and section 5 to make explicitly clear that this application is about vaccine trials. 2. To update the wording in section 5(e) and replicate that wording in section 5(a). 3. Noting the target to recruit 6,000 participants, to provide an estimate of the number of overall contacts required to achieve that figure. 4. In respect of pre-screening: a. To update section 5 to make clear re that pre-screening can be undertaken by NHS Digital, and b. to quantify in terms of likely loss of potential cohort members from the pre-screening 5. To remove reference to 'pseudonymised data' flowing to the applicant. It was agreed the condition would be approved OOC by the IGARD Chair.
2.6	<u>NHS North Central London CCG: DSfC - NHS North Central London CCG - RS, COMM & IV (Presenter: Bethan Thomas) NIC-362253-J5V8L</u> **Application:** This was an amendment application to add the e-Referral Service (e-RS), Personal Demographic Service (PDS) and the Summary Hospital-level Mortality Indicator (SHMI) datasets. The application has also been amended to add the correct name of Microsoft Limited as a Data Processor.

	The overall purpose is for Invoice Validation (IV), which is part of a process by which providers of care or services are paid for the work they do, Risk Stratification (RS) which is a tool for identifying and predicting which patients are likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. **Discussion:** IGARD noted that the newly formed NHS North Central London CCG was "…*expected to publish their own DSPT* by 31/03/21*…" and that the five previous CCGs (NHS Camden, NHS Barnet, NHS Enfield, NHS Haringey, NHS Islington) had published their standards on the 25 March 2020. IGARD asked that a statement be included in section 1 (Abstract) that the NHS Digital DSPT team were assured that during the first year of the newly formed entity, and whilst waiting for the new entity's first DSPT, that appropriate protections were in place for NHS Digital data. *DSPT – Data Security and Protection Toolkit Noting the number of additional datasets requested, IGARD asked that section 5(a) (Objective for Processing) be updated to clearly outline how the additional data added would be contributing to the processing outlined, and that this be mapped to section 5(c) (Specific Outputs Expected). IGARD noted reference in section 5(d) (Benefits) to "…*improved patient experience through more effective commissioning of services*…" and suggested that this statement be updated to also include *"health outcomes"*. Noting that this was a new entity, made up of five previous CCGs, IGARD suggested that section 5(d)(iii) (Yielded Benefits) be updated to include key examples of the original CCGs benefits and how they have accrued to health and social care. **Separate to this application**, IGARD noted this was a new templated application which included PDS, e-RS and SHMI data as a combined class action and were content that for this class action only, that NHS Digital progress these applications via the relevant Precedent route, rather than applications of this type being presented to IGARD for recommendation. **Separate to this application**, NHS Digital noted that work was ongoing to update the CCG templated application standard wording and that more information would follow in due course. **Outcome:** recommendation to approve The following amendments were requested: 1. To include in section 1 a statement from the NHS Digital DSPT team that they are assured that during the first year of the newly formed entity, and whilst waiting for the delivery of the new entity's first DSPT, that there are appropriate protections in place for NHS Digital data. 2. To include within section 5(a) how the data sets are adding to the processing outlined, **and** to map to section 5(c). 3. To update section 5(d) to refer to "*health outcomes*" in addition to "*patient experience*". 4. Noting this was a new entity, to update section 5(d)(iii) with key examples from the original CCG's of how benefits have accrued to health and social care.
2.7	Royal Surrey NHS Foundation Trust: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Bethan Thomas) NIC-225927-H5J7J

	Application: This was a new application for pseudonymised National Cancer Waiting Times (CWT) Monitoring Dataset to allow performance to be measured against operational cancer standards, to cover the period from first referral to first definitive treatment for cancer and any additional subsequent treatments; to determine whether the operational standard(s) that apply were met or not for the patient and the accountable provider(s). The application had previously been presented to IGARD on the 8th August 2019 and IGARD had recommended for approval subject to conditions. NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 8th August 2019 and reviewed as per usual process. **Discussion:** IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD discussed the outstanding conditions and provided further clarification, detailed below, but noted that they remained outstanding. IGARD members noted that Data Controllership was an assessment of fact and noting that NHS Digital's assessment of the Data Controllership had not been provided, reiterated their request that a brief explanation be provided as to why other members of the Cancer Alliance had not been considered joint-Data Controllers. In addition, a copy of the assessment should be uploaded to NHS Digital's Customer Relationship Management (CRM) system. IGARD reiterated their previous query with regard to why the applicant had requested CWT on behalf of the Cancer Alliance. IGARD noted that CCGs within the Cancer Alliance already held this data and asked that a brief explanation be provided as to how the Cancer Alliance handling of the data differed from the CCG's use of the data. **Outcome:** IGARD were unable to make a recommendation because the substantive points raised previously when reviewed by IGARD on the 8th August 2019 had not been addressed. IGARD reiterated the outstanding points namely: 1. To provide a brief explanation of why the other members of the Cancer Alliance are not also considered joint Data Controllers. 2. To clarify why the applicant has requested CWT on behalf of the Cancer Alliance, since individual CCGs forming part of the same Cancer Alliance had previously requested this dataset (for example to provide a brief explanation of how the Cancer Alliance handling of the data may be different from the CCG use of the data).
3	<u>Returning Applications</u> Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role. IGARD requested that future agendas included returning applications and that this commence from 5 November 2020, since it was a key part of their oversight and assurance role.
4	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part

	of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 27th October 2020 can be found attached to these minutes as Appendix B.
5 **5.1**	AOB: Optum Health Solutions UK Limited as a Data Processor NHS Digital asked if consideration could be given to where Optum Health Solutions UK Limited (referred to as 'Optum') is being included as a Data Processor on CCG applications, this could be done by way of notification to IGARD for inclusion on the out of committee (OOC) report appended to published minutes, in the same way that Liaison Financial Services (referred to as 'Liaison') inclusion is notified. IGARD were content with this approach to include the NIC number and organisation in the OOC report in respect of both Optum and Liaison. 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 23/10/20

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-390154-Z4M0F	Public Health England	01/10/2020	1. In respect of the outstanding PAG points raised: To ask PHE to review the specific PAG requirement for PHE to demonstrate that they have GP representation in their governance / decision making processes, and to share the PHE response with PAG and for PAG to confirm their satisfaction with that response.	IGARD Members	Quorum of IGARD members	*"With regard to the issue of identifiers in amendment 8 the application does make reference to future linkages coming back through the DARS IGARD process, presumably the identifiers would be required to perform those linkages. If this is correct, IGARD have asked that this is made explicit in any returning applications or renewals."*

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

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, 27th October 2020

In attendance (IGARD Members):	Paul Affleck (Specialist Ethics Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr Geoffrey Schrecker (Specialist GP Member / Deputy Specialist Chair)
In attendance (NHS Digital):	James Gray (DARS)
	Karen Myers (IGARD Secretariat)
	Heather Pinches (DARS)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual 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-411161-G4K7X University of Oxford **Background:** this was a new application to provide University of Oxford with Pillar 2 testing data in order to aid recruitment into the Platform Randomised trial of Interventions against COVID-19 In older people (PRINCIPLE). The PRINCIPLE study is the only national urgent public health priority trial evaluating therapeutics for COVID-19 in the primary care setting, endorsed by the Chief Medical Officers of the four devolved nations (England, Scotland, Northern Ireland and Wales). The study aims to find out whether early treatment in the community speeds recovery and reduces the need for hospital admission for those with COVID-like illnesses and is currently recruiting via GP practices and their website. However to rapidly increase the current cohort of circa 1000 participants to 3000 and beyond, the University would like to receive names and contact details from the Pillar 2 testing system, randomised, and aged 50 and over who have received a positive COVID-19 test in the previous 24 hours. NHS Digital noted that the draft application presented was in the early stages of discussion and that talks were ongoing with the applicant on a number of key topics including, but not

	limited to, updating ethics, national data opt-outs, updating relevant privacy notices and recruitment to the study. The following observations were made on the basis of the draft application only. **IGARD Observations:** IGARD members noted that the work being undertaken by the University was extremely important and supported the study, since the outcomes may keep those testing positive from COVID-19 out of a hospital setting and ultimately reduce morbidity and mortality from COVID-19. Accordingly, IGARD members stressed that comments on the draft application were made with the intention of maximising and increasing participant take up to the study. NHS Digital noted that application would likely be proceeding via the SIRO Precedent route due to the urgency of the draft application but had been brought to IGARD for advice. NHS Digital noted t future amendment applications and relevant supporting documents would return to IGARD for advice. IGARD welcomed that approach. In terms of the weekly data destruction outlined in the draft application, IGARD members suggested that the applicant may wish to consider if there needs to be a retention of the data for a longer period, which may ensure that contact is not repeated should, for instance, a citizen have repeated positive COVID-19 test results. NHS Digital noted that they would explore with the applicant a feed back mechanism from the University's contact centre to NHS Digital to capture any verbal 'opt outs' – which would ideally prevent those Pillar 2 data subjects' contact data being shared with the same (or different) researchers in the future. Careful thought also needs to be given to how phone calls are logged and recorded so that all contact information is appropriately destroyed when required. NHS Digital noted that the University's, DHSC's and NHS Digital's privacy notices would need to be updated, as advised by NHS Digital's information governance (IG) directorate. IGARD agreed that the privacy notices would require an update, however, in terms of transparency in general – and to increase the likelihood of a positive reception by recipients of a "cold call" - suggested trying to work into the process a notification to the patient / public earlier in the testing journey. Trying to reduce the element of surprise at every opportunity where there was contact with the testing subject is vital and IGARD suggested that all avenues were explored to try to work this in to patient communications (eg text messages) as early as possible to advise that should they receive a positive COVID-19 test result they may be contacted by researchers as soon as 24 hours of that result to be invited to take part in research. In addition, IGARD members noted the need for a robust system to ensure that the University were not the first contact for anyone receiving a COVID-19 positive result and NHS Digital confirmed that they were exploring the Pillar 2 database to ensure this small but potentially serious risk was mitigated. Noting the demographic of the cohort would be 50 years or older, IGARD members wondered if consideration had been given to those that did not have access to the internet and that consideration be given to potential participants being able to join the trial by phone. IGARD members noted the applicant's endeavours to recruit to the study via the website and GP practices and noted the robust reasons given why this was not recruiting participants quickly enough and why new avenues needed to be explored. IGARD queried whether NHS Test and Trace Service could be utilised. IGARD suggested that, for transparency, section 5 be updated to elucidate why the applicant was not utilising test subjects' GP Practices or the

	NHS Test and Trace Service since both would have already have the contact details of the individual and be informed of the test result. IGARD members also supported the development of the permission to contact work being undertaken as part of the testing process and that thought should be given to how to build this into the work of the Test and Trace call centre script, in the long term. Noting that Health Data Research UK (HDRUK) were supporting the applicant with public and patient engagement, IGARD members also suggested that, given the wide range of public being contacted, that more general gauging of public opinion be sought (as well as the useful engagement of expert patients). In addition, NHS Digital noted that some NIHR staff would be supporting the applicant in their call centre to contact potential recruitees to the study and IGARD members suggested that consideration be given as to whether NIHR were an additional Data Processor (by considering the facts of their involvement and as laid out in NHS Digital's DARS standard for Data Controllers / Data Processors). IGARD members noted and endorsed NHS Digital's suggestion that ethical approval be sought and obtained for this new mode of recruitment to the trial. Noting that there is a legal gateway via the Health Service Control of Patients Information (COPI) Regulations 2002, IGARD members suggested that it be clearly articulated that all the necessary steps had been taken to satisfy the relevant limbs of these Regulations, including documentary evidence of endorsement from the four CMO's of the devolved nations. IGARD members discussed national data opt-outs and supported NHS Digital's view of applying them in this context. In addition there was a discussion with regard to the telephone preference service (TPS) and IGARD members noted that the applicant consider applying TPS due to the fact that there may be a good reason why people had applied via TPS not to be contacted by telephone, such as those that are particularly vulnerable and who may be distressed by "cold callers". IGARD members noted that they had not seen any supporting documentation but suggested that the applicant ensure that when people sign up to the consent materials that said materials are future-proofed in terms of any long term follow up and linking data held by NHS Digital under other applications. IGARD members noted that the tables in section 3 should be updated to reflect that the data was confidential and that the application be updated throughout to correct any typos which may affect the meaning of the information provided. Separate to the draft application presented, IGARD suggested that NHS Digital may wish to draft a Pillar 2 Precedent for consideration by IGARD, the Caldicott Guardian, IG and the Office of the Data Protection Officer, which may provide an additional level of oversight and assurance if there are urgent applications in future.. <u>Screening</u> **Background:** NHS Digital gave a verbal update with regard to screening for trials and access to the patient's summary care record (SCR), noting that the SCR is excluded from use for research. The following observations were made on the basis of the verbal briefing only.

	IGARD Observations: IGARD members welcomed the verbal update from NHS Digital and noted the burden on GP practices during the pandemic to provide to researchers a copy of the patient's SCR. NHS Digital advised that a number of potential cohort members had had to be dropped from the trial because the University had been unable to gain access to the patient's SCR via their GP. The applicant wanted access to the SCR after the patient had consented to be part of the trial in order to assess if any of their health issues or current medication may affect them being part of a clinical trial or interact with drugs being used on the clinical trial. Noting that the applicant did not want to rely solely on patient self-reporting, other avenues such as utilising the GP Data for Planning and Research were discussed and it was agreed that it would not be an efficient use of that dataset given the necessary flows of data in and out of NHS Digital and the time it would take. In light of this, IGARD members observed it was vitally important for the clinical trial team to be able to utilise the SCR to ensure patient safety and ensure sufficient safeguards were in place. It was thought that if cohort members provided their consent for their SCR to be used in this way, coupled with the direct care element of the trial, this may provide a sufficient legal gateway, notwithstanding that it was part of a wider research study. NHS Digital noted that talks were still at an early stage with both the applicant and NHS Digital's information governance directorate (IG) / Caldicott Guardian, and would come back to IGARD with further information in due course.
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.