Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 2 July 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Dan Goodwin	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics (Observer: 2.1 to 2.5)
Karen Myers	IGARD Secretariat
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
Tom Wright	Data Access Request Service (DARS)

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. Imran Khan noted a professional link to NIC-218380-R8L2R (Imperial College London) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.

	Maurice Smith noted a professional link to NIC-218380-R8L2R (Imperial College London) 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 25th June 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>Personal Demographic Service (PDS) Briefing note (Presenter: Tom Wright)</u> The briefing paper was to inform IGARD about the applications to receive PDS data for commissioners and is to be made available to commissioners through the Data Access Request Service (DARS). The primary purpose of processing PDS data by NHS Digital is to enable the correct operation of the PDS system and support direct care, although the data extracted from PDS may also be supplied for secondary uses. IGARD welcomed the briefing paper and looked forward to receiving an updated paper alongside the first application for commissioners. IGARD made the following additional comments: 1. To provide some generic examples within paragraph 4.1 of how commissioners might use the PDS data, for example, for data quality, verifying patient details and to identify care home flags. 2. To update paragraph 6.3 to make it clear that the de-identified data can still be re-identified. 3. To consider if *"gender"* accurately reflects the data sitting within PDS.
2.2	<u>NHS Buckinghamshire CCG: commissioning, risk stratification, invoice validation (Presenter: Duncan Easton / Dan Goodwin) NIC-186888-X2K6T</u> **Application:** This was an amendment application to receive data for the purpose of adding e-Referral (e-RS) data for commissioning purposes and Prescribing Services as a data processor for the purpose of Risk Stratification as part of the region's COVID outbreak response in order to effectively identify patients flagged as priority by the Chief Medical Officers. 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 at high risk or likely to be at high risk and prioritising the management of their care; and to provide intelligence to support the commissioning of health services. NHS Digital noted that they had updated the application to correctly list the Microsoft legal entity in both section 2 (Locations) and section 6 (Special Conditions). **Discussion:** IGARD noted the update from NHS Digital in respect of the updates to section 2 and section 6 to correctly list the Microsoft legal entities. IGARD noted and thanked the applicant for acknowledging comments previously made by IGARD in respect of the privacy notice being updated to accurately reflect any automated decision making that would be taking place.

	IGARD queried the references to *"Johns Hopkins ACG"* within the application, and noted that it was not clear what their role was, and asked that a suitable explanation was provided in section 5 (Purpose / Methods / Outputs), of the involvement and activities of Johns Hopkins ACG, including what data, and the type of data that they may or may not have access to. IGARD queried the information provided in section 1 (Abstract) that stated some of the data requested was to support the CCG's region response to COVID-19, and asked that further information of this was provided in section 5(a) (Objective for Processing), which should include further information on the COVID-19 purpose and the processing related to this. IGARD noted that a number of Data Processors were listed within the application, and asked that section 5 was updated to clearly outline for each Data Processor, what their specific processing was, and to ensure that there was no duplicate processing or duplicate handling of NHS Digital data. In addition, IGARD also asked that a further explanation was provided of the processing carried out in respect of the 'NHS England Wave 2 PHM Project', as referred to throughout section 5, noting that this was a time limited project. A number of acronyms were noted in section 5 and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use were expanded, clearly defined and that that a supportive explanation in a language suitable for a lay reader, for example (and not limited to) to expand the "*DSCRO*" acronym. IGARD queried the reference in section 5(b) (Processing Activities) to a specifically named individual and asked that this was revised since it is not appropriate to limit access to one named individual within a Data Sharing Agreement (DSA), and that consideration was given to replacing this with a role-based title. IGARD noted that section 5(d) (Benefits) (iii) (Yielded Benefits) included an outline of yielded benefits but no specific detail and suggested that NHS Digital worked with the applicant to continue developing the yielded benefits section. In addition, IGARD advised that they had provided NHS Digital with suggestions for updating the CCG template wording, for example in relation to the yielded benefits, and advised that they would be happy to work with NHS Digital to continue developing this. **ACTION:** IGARD noted that they had provided NHS Digital with suggestions for updating the template wording and advised that would be happy to work with NHS Digital to continue developing this. **Outcome:** recommendation to approve subject to the following condition: 1. To provide a suitable explanation in section 5 of the involvement and activities of Johns Hopkins ACG, including what data, and the type of data that they may or may not have access to. The following amendments were requested: 1. To update section 5(a) to include further information on the COVID-19 purpose and the processing related to this. 2. To update section 5 to clearly outline for each Data Processor what their specific processing is and ensure that there is no duplicate processing or duplicate handling of NHS Digital data. In addition, to provide further explanation of the processing carried out in respect of the NHS England Wave 2 PHM Project. 3. To amend section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader, for example DSCRO. 4. To revise the reference in section 5(b) to a *"specific named individual"* and consider replacing this with a role-based title.

	The following advice was given: 1. IGARD suggested that NHS Digital work with the applicant to continue developing the yielded benefits section. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.3	<u>Monitor (NHS England / NHS Improvement): inclusion of exception basis conditions for sharing unsuppressed data / metrics with restricted organisations under additional IG controls (Presenter: Louise Dunn) NIC-15814-C6W9R</u> **Application:** This was a renewal application to receive pseudonymised Community Services Data Set (CSDS), Hospital Episode Statistics (HES), Secondary Uses Service (SUS) Payment by Results (PbR), Civil Registration (CR), Mental Health Services Data Set (MHSDS), Mental Health Minimum Data Set (MHMDS), Improving Access to Psychological Therapies Data Set (IAPT), Patient Level Costing Acute Data Set, Patient Reported Outcome Measures (PROMs) and Diagnostic Imaging Dataset (DIDs) data for a further 12 months. It was also an amendment to request to permit the sharing of aggregated data where it may be required in some stances that small numbers are not suppressed. The application seeks to request data for both the NHS Trust Development Agency, NHS England / NHS Improvement, and Monitor as join Data Controllers and will be used to support the delivery of the applicant's statutory function and support direct improvement and / or oversight of Trusts. The application had previously been recommended for approval for three months on the 26th March 2020. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 26th May 2020. IGARD had a lengthy discussion on the breadth and scope of the complex application and in particular discussed the amendment request to permit the sharing of aggregated data where in some instances that small numbers would not be suppressed. IGARD asked that to further support this request, NHS Improvement should furnish an appropriate Data Protection Impact Assessment (DPIA), which addressed the risk of unsuppressed data being received, and contained a further analyses of the further onward sharing and inclusion of exception basis conditions for sharing of unsuppressed data / metrics with restricted organisations under additional Information Governance (IG) controls. IGARD also asked that a special condition was inserted in section 6 (Special Conditions) that a register of where and when NHS Digital data has been shared with small numbers unsuppressed would be kept and that this would be shared with NHS Digital on a quarterly basis. There was a lengthy discussion with regard to the quantum of data requested and IGARD asked that in light of the large dataset requested that an appropriate justification was provided, in line with NHS Digital's Data Minimisation Standard 3 and to evidence compliance with the General Data Protection Regulation (GDPR). IGARD advised that section 5(b) (Processing Activities) would need to be revised, re-written, or broken down into separate applications by the time of renewal of this application and before it was presented back at IGARD, and that NHS Digital should work with the applicant to progress this. This was due to the enormous breadth and scope of the agreement which had rendered the narrative and description of the processing impenetrable for the lay reader. As part of this reorganisation, section 5 (Purpose / Methods / Outputs) would also need to be written in a language suitable for a lay reader, with suitable explanatory notes.

	A number of acronyms were noted in section 5 and IGARD asked that this public facing section be updated to ensure that all acronyms upon first use were expanded, clearly defined and that that a supportive explanation in a language suitable for a lay reader. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. Noting that one specialist IGARD member dissented from the recommendation to approve (still having concerns about the purpose of the application), a further discussion was held between the IGARD members on the process for reaching a recommendation. IGARD agreed that as per the IGARD Terms of Reference, they would recommend for approval by way of a majority vote of 4 members (Lay Chair, Lay Member, two Specialist Members (approve) to 1 member (specialist) (dissent). **Outcome:** The application was recommended for approval by way of a majority vote of four members to one member, with one specialist member dissenting. The majority recommendation to approve is subject to the following condition: 1. NHS Improvement to furnish an appropriate DPIA, which addresses the risk of unsuppressed data being received and contains a further analyses of the further onward sharing and inclusion of exception basis conditions for sharing of unsuppressed data / metrics with restricted organisations under additional IG controls. The following amendment were requested: 1. To provide an appropriate justification of this large dataset, in line with NHS Digital's Data Minimisation Standard 3 and to evidence compliance with GDPR. 2. To amend section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader. 3. To insert a special condition that a register of where and when NHS Digital data has been shared with small numbers unsuppressed would be kept and that this will be shared with NHS Digital on a quarterly basis. The following advice was given: 1. IGARD advised that section 5(b) would need to be revised / re-written (or broken down into separate applications) by the time of renewal of this application. This is due to the enormous breadth and scope of the agreement which had rendered the narrative and description of the processing impenetrable. As part of this reorganisation, section 5 would also need to be written in a language suitable for a lay reader, or with suitable explanatory notes. 2. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.4	<u>University College London (UCL): MR1318 General health and hospitalisation admission in children born after ART – a population based linkage study (Presenter: Louise Dunn) NIC-180665-GJMW5</u> **Application:** This was an extension application for pseudonymised Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data, to allow further time to process the data once made available; and an amendment to add Civil Registration (birth) data. UCL

	were requesting access to data on maternal age at the time of delivery for the existing study cohorts, consisting of children conceived after Artificial Reproductive Therapies (ART), related spontaneously conceived siblings controls and unrelated matched spontaneously conceived population controls. The aim of the study is to establish if children born after assisted conception (including IVF and related techniques) are at an increased risk of specific diagnoses compared to spontaneously conceived siblings and unrelated spontaneously conceived controls. NHS Digital advised IGARD that the s251 support from the Health Research Authority Confidentiality Advisory Group (HRA CAG) had been extended until 2022 and that the appropriate Ethics Approval had also been extended to support the completion of the study. NHS Digital also confirmed the figures for the various cohorts were 86,000 for children born via Assisted Reproductive Technologies (ART), 23,000 in the siblings cohort and 172,000 in the control cohort; and advised that the application would need updating further to reflect this information. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted the information provided by NHS Digital in relation to the cohort numbers and asked that section 1 (Abstract) and section 5(a) (Objective for Processing) was updated to confirm the cohort numbers for all the groups. In addition, IGARD also queried what the control cohort was matched on since it was not clear in the application or supporting documents provided, and asked that clarification was provided in section 5 (Purpose / Methods / Outputs) and that the children born after ART were also included. In relation to the s251 support from HRA CAG, IGARD noted the update from NHS Digital that this had been extended to 2022. IGARD asked that a copy of the original HRA CAG application was provided to ascertain what the original study aim was and in addition asked that any further amended application(s) that had been submitted to HRA CAG should also be provided since this was now a longitudinal study into a wide variety of factors and health outcomes, not just mortality. In addition, IGARD also asked that copies of the original HRA CAG application and the amendment HRA CAG application(s) be uploaded to NHS Digital's Customer Relationship Management (CRM) system as future supporting documentation. IGARD noted that the study protocol that they had been provided with was from 2013 and requested that if a more recent version of this document was available, that this was provided to NHS Digital and that a copy be uploaded to NHS Digital's CRM system. In addition, IGARD also noted that the relevant Ethics approval had been extended and asked that a copy of the Ethics approval was also uploaded to NHS Digital's CRM system. IGARD noted in section 5(a) that families connected to ART had been consulted with, in relation to the research outcomes in the past, and asked for confirmation that this patient and public involvement (PPI) had been maintained. IGARD also queried how the outputs of the study would be disseminated further, and asked for confirmation of this be provided in section 5. IGARD queried the statement in section 5(a) to *"abnormal foetal presentation"* and asked that further clarification of this was provided, noting that this was open to at least two interpretations of presentation of baby at delivery or status of baby after delivery. IGARD noted the reference in section 5(b) (Processing Activities) to the applicant receiving the ***"****deprivation score"* from NHS Digital, and asked that a further explanation was provided of

	why this was being used, since it was not clear in the application or supporting documents provided. IGARD noted the reference within the application to the Office for National Statistics (ONS) data, and asked that section 5 was updated with confirmation that NHS Digital now handles this data on behalf of ONS. IGARD queried why the applicant was requesting the HES data and asked that section 5(a) was amended to provide a clear justification for requesting the HES data and how this linked to the study purpose. IGARD queried the references in section 1 and section 5(a) to *"poor quality of the maternal age"*, and asked that it was made clear that this related to the quality of the data, and **not** the Mother. IGARD noted the reference in section 1 to the Data Sharing Agreement (DSA) being extended for 1-year, and asked that this was updated to correctly reflect the proposed DSA end date of 2023. IGARD noted the references within section 1 and section 5(a) (Objective for Processing) to *"delivery"* and suggested that the word "*delivery*" was replaced with the term *"birth"*. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** recommendation to approve subject to the following condition: 1. To provide a copy of the original HRA CAG application and any further amendment applications submitted to HRA CAG, to support the fact that this is now a longitudinal study into a wide variety of factors and health outcomes, not just mortality. The following amendments were requested: 1. To upload a copy of the original HRA CAG applications and the recent HRA CAG applications to NHS Digital's CRM system. 2. In respect of the PPI: a) To confirm if the PPI initiative referred to has been maintained. b) To confirm how the outputs of the study will be disseminated further. 3. To update section 5(a) to provide further clarification on the statement *"abnormal foetal presentation"* (as it is open to at least two interpretations). 4. To provide an explanation of why the ***"deprivation score"*** is being used. 5. To update section 5 to confirm that NHS Digital now handles the ONS data. 6. To amend section 5(a) to provide a clear justification for requesting the HES data and how this links to the study purpose**.** 7. To provide and upload a copy of the new study protocol and Ethics approval to NHS Digital's CRM system. 8. To update section 1 to remove reference the 1-year extension and to reflect the proposed DSA end date of 2023. 9. To update section 1 and section 5(a) to confirm the cohort numbers for all groups. 10. To clarify in section 5 what the control cohort is matched on and to include the children born after ART. 11. To replace the reference to *"delivery"* in section 1 and section 5 with *"birth"*. 12. To make clear that the reference to *"poor quality"* of Maternal age related to the quality of the data, not the mother. The following advice was given:

	1. IGARD noted that the applicant could apply for funding from The Wellcome Trust to maximise the impact of the research and suggested that they consider doing this, given that the research findings may be of particular interest and have a significant impact in both the UK and world-wide. It was agreed the condition would be approved out of committee (OOC) by IGARD Members.
2.5	<u>Imperial College London: patient choices and provider quality, why patients change GPs (Presenter: Louise Dunn) NIC-218380-R8L2R</u> **Application:** This was a new application for pseudonymised record level extract of England patients listed in the Personal Demographics Service (PDS) dataset data over a 5 year period (2015/16 to 2019/20) to try to understand why an individual moves their GP practice. The research team, cantered in the Economics and Public Policy Department within the Business School, are requesting data as part of a wider programme of researching investigating patients choices over GP providers and the project is looking specifically at how patients chose their GP, and when and why they switch their GP over time, to try to understand the factors involved with a change of GP. **Discussion:** IGARD had a lengthy discussion on the purpose of the application, noting that this was not clear from the application or supporting document 1, the study protocol that had been provided as part of the review. In particular IGARD noted the statement that *"the goal of the project is to quantify how often online reviews on the NHS Choices website cause individuals to switch to higher-ranked GPPs"* and that the intention of the study was to help understand how individuals chose their GPP, so enabling the applicant to make recommendations that would improve how the NHS Choices website provides information to individuals. IGARD queried how this would be achieved, noting that the NHS Choices website no longer existed. In addition, IGARD also queried the impact on patient choice following a GPP closures, noting that such closures were rare. In light of this, IGARD asked that the applicant review the purpose of the application, in particular (and not limited to) the references throughout section 5 (Purpose / Methods / Outputs) to *"NHS Choices"*, noting that this website and entity no longer existed, and does not have any direct replacement. IGARD also asked that the study protocol be updated to provide further meaningful information and background to the study as outlined in the to be updated application, since it was extremely brief. IGARD also noted that within the study protocol, there was a reference to *"higher ranked GPPs"* and asked for further information on the meaning of this since there is no ranking system within England for GPPs. IGARD queried the conflicting information provided within the study protocol and the data access requested in the application, for example, the protocol stated that mortality data was required, however the application did not reflect this requirement. In light of the General Data Protection Regulation (GDPR) Article 6 and Article 9 basis referenced that stated the processing was in the public interest, IGARD queried exactly what the public interest in the study was. IGARD concluded that a public interest in the processing of the data requested was lacking and therefore that the stated legal basis that processing was necessary, has not been established. IGARD noted the benefits outlined in section 5(d) (Benefits) and asked that these were reviewed further by the applicant, for example in relation to the reference to *"NHS Choices"*. IGARD noted that the acronym *"GPP"* (General Practitioner Practice) was not used consistently throughout the application and sometimes referring to the practice and sometimes referred to the GP themselves, and asked that the application was updated to ensure

	consistency throughout; and that where *"GP closures"* was referenced, that this was amended to correctly refer to *"GPP closures"*. In respect of patients switching GPP's, IGARD noted that a CCG in some areas of England can put restrictions on where and how patients can switch practices following a GPP closure, and asked that the application was updated clarifying this point. In addition, IGARD also noted the reference(s) within the application to patients switching GPP's and asked that further clarity was provided on how this had been assessed; and that acknowledgement was provided within the application that in many parts of England, there was little or **no** opportunity to change GPP. IGARD noted the strong statement in section 5(a) (Objective for Processing) that the study would *"improve health outcomes for patients and economic outcomes for the NHS"* and asked that this was reviewed and justified further. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, and suggested that the applicant consider producing a study specific General Data Protection Regulation (GDPR) compliant Privacy Notice. IGARD queried who was funding the study, and asked that section 8(b) (Funding Sources) was updated with the source(s) of the funding. IGARD queried the information provided in section 1 (Abstract) in relation to cohort 3 *"Postcode and GP Practice Code are the same and the change is for some other reason"* and asked that further clarity was provided, including what combination of patients and GPP this covered. IGARD noted the applicant was requesting demographics data and asked that section 3 (Datasets Held / Requested) was updated to clarify what was in this dataset. IGARD noted the second special condition in section 6 (Special Conditions) that stated *"The Data Controller should ensure appropriate data processing agreements with all data processors contracted to undertaking work referenced within this agreement."* and asked that this was reviewed, and noting there was only one Data Processor, asked that the reference to *"all Data Processors"* was removed*;* or if there was an additional Data Processor, that they were added to section 1(c) (Data Processors) of the application. IGARD queried the references throughout the application to *"English patients"* and queried if for instance it referred to those registered with a GPP in England, or who identified as English or who lived in England for example, and asked for further clarity of what was meant by this term be provided in section 5. IGARD queried the inconsistences within the application when referring to the identifiers held by NHS Digital and asked that this was revised to ensure that where appropriate the term '*gender*' was replaced with the term '*sex*', if '*sex*' was the data set held by NHS Digital. **Outcome:** Unable to recommend for approval 1. To review the purpose of the application: in particular, the reference to *"NHS Choices"*, noting that this website and entity no longer exist, and does not have any direct replacement. 2. To clearly establish the public interest in the study since the stated legal basis that processing is necessary, has not been established. 3. To ensure consistent use of the acronym *"GPP"*, and where *"GP closures"* is referenced, this should be amended to refer to *"GPP closures"*. 4. In relation to the GPP closures, to provide further clarity within the application that a CCG can put restrictions on where and how patients can switch practices.

	5. To provide further clarity on the reference(s) to individuals switching GPP's and how this has been assessed. 6. To acknowledge within the application that in many parts of England, there is little or **no** opportunity to change GPP. 7. To provide further information on the reference within the protocol to *"higher ranked GPPs"*. 8. The applicant to consider producing a study specific GDPR compliant Privacy Notice. 9. To update the source(s) of funding in section 8b. 10. To update the study protocol to provide further meaningful information and background to the study as outlined in the application. 11. To review the benefits outlined in section 5(d), for example in relation to the reference to *"NHS Choices"*. 12. To review and justify the statement in section 5(a) that the study will *"improve health outcomes for patients and economic outcomes for the NHS"*. 13. To provide further clarity of cohort 3 in section 1, and confirm what combination of patients and GPP this covers. 14. To update section 3 to clarify what is in the demographic dataset referred to. 15. To review the second special condition in section 6 and remove the reference to *"all Data Processors"*, or if there is an additional Data Processor, to add to section 1(c) of the application. 16. To provide further clarity on the references to *"English patients"* throughout the application and what is meant by this term. 17. To ensure that where appropriate the term *"gender"* is replaced with the term *"sex"*.
2.6	<u>Private Healthcare Information Network (PHIN): PHIN private healthcare market investigation CMA order 2014 (Presenter: Kimberley Watson) NIC-13906-G0F3F</u> **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) and Patient Reported Outcome Measures (PROMs) data on a quarterly basis; and an amendment to remove the request for HES linked to PROMS data although PHIN will retain the data already disseminated and will continue to process it in line with its original use. In April 2015, the Competition and Markets Authority (CMA) designating PHIN as the official information organisation and requesting all hospitals providing private healthcare in the UK to submit information relating to each episode of care relating to private patients. PHIN also needs to compare and benchmark private activity with NHS data. PHIN's overarching mission is to enable patients to be able to make better informed choices about their healthcare providers and through the provision of comparative information to help private providers to continuously improve their care and clinical outcomes. **Discussion:** IGARD noted that this application had last been independently reviewed by its predecessor the Data Access Advisory Group (DAAG) in 2016 and before the General Data Protection Regulations (GDPR) came into force in 2018. IGARD also noted that when application had been reviewed previously by their predecessor DAAG, they had specifically raised a query asking for clarification of which representative bodies the applicant intended to consult with and asked for confirmation of whether this had been addressed, and if so how. IGARD queried how the stated Article 6 GDPR legal basis could be relied on for all aspects of the processing, beyond the scope of the Competition and Markets Authority (CMA) Order, for example in relation to addressing the Care Quality Commission (CQC) queries as outlined in section 5(a) (Objective for Processing), which related to PHIN's wider function, not just those set out in the Order. IGARD suggested that a clear justification was provided in section 1

	(Abstract) and section 5 (Purpose / Methods / Outputs) or the applicant consider whether another Article 6 legal basis could be considered, in addition to that already provided. Although there was an Article 6 GDPR legal basis referenced in section 5(a), this would also need updating to make specific reference to the Article 9 GDPR legal basis; and to ensure the appropriate Article 6 legal bases were referenced to cover **all** processing outlined in this application. IGARD noted the statement in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and/or Social Care) *"The CMA Order enables PHIN to licence this PHES data to interested external third parties…"*, and asked that further clarity was provided on this; including confirmation of what this comprised of, and if any NHS Digital data was being onwardly shared, since it was not clearly within the application. IGARD queried the references within section 5(c) to *"users"* and if these were the *'consultants'*, for example *"…it will not be possible for users to move this data to another location…"*, and asked for confirmation of who the users were. It was noted that section 1 (Abstract) would need amending to use the full agreed wording from the NHS Digital Security Adviser regarding Cloud Storage. IGARD noted the references in section 1 and section 5(d) (iii) to *"PROMs"* and *"QPROMs"* data, and asked that these were updated to provide a clear explanation of these terms. IGARD queried the references in section 5 to *"NHS Choices"* and asked that this was removed as this website no longer exists. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that upon renewal, consideration should be given to describing any commercial aspects, for example, does PHIN charge a fee to NHS or any other organisation(s) for providing this service, and whether or not there was the possibility of private hospitals / consultants gaining financial benefits from these outputs. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's Precedent route. **Outcome:** recommendation to approve subject to the following condition: 1. To provide a clear justification of how the stated Article 6 legal basis can be relied on for all aspects of the processing beyond the scope of the CMA Order, for example in relation to addressing the CQC queries as outlined in section 5(a), which relate to PHIN's wider functions, not just those set out in the Order. The following amendments were requested: 1. To provide further clarity on the reference in section 5(d)(ii) to *"The CMA Order enables PHIN to licence this PHES data to interested external third parties…"*, and to confirm what this comprises and if any NHS Digital data is being onwardly shared. 2. To confirm if the point raised previously by DAAG in relation to the interaction with the other *"representative bodies"* and how this had been addressed. 3. To provide confirmation of who the *"users"* are referred to in section 5(c). 4. To update section 5(a) to make specific reference to the Article 9 GDPR legal basis, and to ensure the appropriate Article 6 legal bases are referenced to cover **all** processing outlined in this application.

	5. To amend section 1 to include NHS Digital's Security Advisor's advice on Cloud storage and to use the full agreed wording. 6. To update section 1 and section 5(d) (iii) to provide a clear explanation of what PROMs and QPROMs refer to. 7. To remove references to *"NHS Choices"* in section 5 as this no longer exists. The following advice was given: 1. IGARD suggested that upon renewal, consideration should be given to describing any commercial aspects, for example, does PHIN charge a fee to NHS or any other organisation(s) for providing this service, and whether or not there is the possibility of private hospitals / consultants gaining financial benefits from these outputs. 2. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair
2.7	<u>University of Birmingham (UoB): MR1257 CReST Trial (role of endoluminal stenting in the acute management of obstructing colorectal cancer extension request for patient tracker service (Presenter: Kimberley Watson) NIC-178135-HJSFF</u> **Application:** This was a request to extend the current agreement which expired on the 16th March 2017. The Birmingham Clinical Trials Unit (BCTC) at UoB requited to continue to hold identifiable data relating to the date and cause of death, including the incidence and the outcome of any cancers, of any participants who consented to participate in the full ColoRectal Stenting Trial (CReST). CReST was a large, pragmatic phase III multi-centre randomised controlled trial aiming to establish if endoluminal stenting, rather than emergency surgery, for patients admitted acutely with large bowel obstructions can reduce perioperative morbidity (as assessed by length of hospital stay) and reduce the 30-day mortality. **Discussion:** IGARD noted that the Ethics approval for this application was from 2008, and asked that written confirmation was provided that an Ethics Annual Review had been submitted on an annual basis in line with the terms of the original Ethics approval. IGARD queried the references within the application to *"The Results will …",* and asked that the application was amended throughout to more accurately reflect that *"The results **may**…"*. IGARD noted that the applicant stated they had presented to NICE and that they *"hope that NICE will take into account the findings of CReST and amend their guidance accordingly should there be the need"*. IGARD noted that NICE has had as yet unpublished CReST data presented to its guideline committee by one of the CReST trialists as expert witness evidence. The relevant guidelines have been impacted as a result. IGARD suggested that the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) were updated further to reflect the full extent of the good work and acknowledgement received by the researchers. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** recommendation to approve subject to the following condition: 1. To provide written confirmation that an Ethics Annual Review has been submitted, in line with the terms of the original Ethics approval.

	The following amendments were requested: 1. To update the application throughout to amend the references from *"The Results will…"* to *"The results may…"*. 2. To update the yielded benefits in section 5(d) (iii) to reflect the full extent of the good work and acknowledgement received by the researchers. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair
3.1	<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 COPI regulation 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 30th June can be found attached to these minutes as Appendix B.
3.2	<u>COVID-19: Information Governance (IG) Data Release Register</u> IGARD discussed NHS Digital's IG Data Release Register - March to May 2020, that had been circulated to members for comments, and agreed that written feedback would be shared with NHS Digital's Executive Director of IG following the meeting, to support this work going forward. In addition, IGARD also agreed, that following a request from NHS Digital, IGARD would provide a retrospective review and provide feedback on a maximum of four of the data requests approved by NHS Digital IG, and that these would be discussed at the IGARD meeting on the first Thursday of each month.
4	<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.
5	<u>AOB:</u> 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 26/06/20

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-121996-T2R7B	University of Bristol	11/06/2020	1. The applicant to provide written evidence (for example an email filenote) of the verbal confirmation from HRA CAG that the support was unconditional and that a supporting letter was forthcoming. 2. To revise section 5 throughout to ensure that: a) the aims outlined in section 5(a) are aligned with the processing outlined in section 5(b). b) confirmation is provided as to whether the mortality data flows are linked to the data on the University of Bristol server.	IGARD Members	Quorum of IGARD Members	*"Since the data being sent to the applicant will bear the applicant's study numbers for linkage to the study data they already hold it should be described as 'identifiable' in section 3b."*
NIC-15293-R6V2H	Health IQ Ltd	11/06/2020	1. In respect of Territory of use: a) To be explicitly clear that the territory of use relates to the applicant's controllership of processing data to feed into the Vantage tool in England and Wales, and how this relates to the reference to the *"worldwide outputs"* within the application. b) To replicate the statement in section 5(a) that states *"Processing of the data is restricted to within England, but outputs are anonymous, aggregate and*	IGARD Members	Quorum of IGARD Members	N/A

			small-number suppressed and therefore could be used worldwide" as a special condition in section 6. 2. In respect of the Vantage tool: a) To provide confirmation of the level of pharmaceutical organisation(s) uptake of the tool and likely involvement, for example, by providing a clear worked example of how they might use the Vantage tool and the outputs. 3. To make it explicitly clear within the application that a Vantage tool user can only see aggregated data with small numbers suppressed and do not at any stage have a view of the underlying record level data.			

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action (addition of Liaison Financial Service and Cloud storage):

- None notified to IGARD

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, 30 June 2020

In attendance (IGARD Members):	Paul Affleck (Specialist Ethics Member)
	Kirsty Irvine (Lay Chair)
	Dr. Geoffrey Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Catherine Day (DARS)
	Louise Dunn (DARS)
	Duncan Easton (DARS)
	Liz Gaffney (DARS)
	Bethan Thomas (DARS)
	Kimberley Watson (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 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	<u>GPES Data for Pandemic Planning and Research (COVID-19) Templates & Briefing Note</u> **Background:** This was an update to the briefing paper presented to the COVID-19 response meeting on the 21 April 2020 and the informal engagement with regard to the CCG and Local Authority templated applications at the BAU IGARD meeting on the 28 May 2020. NHS Digital noted that the GPES Data for Pandemic Planning and Research Data Provision Notice was published on the 14 May alongside the application process, which is specific to this dataset and specifies that all applications will be submitted via the Data Access Request Service (DARS) for review at both the Profession Advisory Group (PAG) and IGARD. Following submission of the templated applications to IGARD, they had been extensively re-worked, and DARS noted they were currently progressing two CCG templates: one for pseudonymised data and one for identifiable data. Both templates were with NHS Digital's

	information governance (IG) for review. NHS Digital noted that the two CCG template applications will be presented to both PAG and IGARD. **IGARD Observations:** IGARD members noted the update to both the briefing note and templated applications and noted that today they had received only one templated application to review: CCG pseudonymised data. IGARD also endorsed DARS' view that the pseudonymised and identifiable data flows should be split into two separate templated applications and welcomed this approach. **Briefing Note observations:** IGARD members noted that since the acronyms for both the GPES Data for Pandemic Planning & Research (GDPPR) and GPES Data for Planning & Research (GPDPR) were very similar, to ensure that throughout the briefing note (and subsequent templated applications) that the correct acronym was being used, since there was distinct difference between the two datasets. IGARD members queried if the Data Services for Commissioners Regional Office (DSCRO) received one data flow from NHS Digital and then flowed two flows onto CCGs as it was not clear from the briefing note, and asked that it was clearly articulated that the DSCRO received one data flow from NHS Digital and then flowed out both pseudonymised and identifiable data flows via two separate flows of data. IGARD members reiterated their advice from the 28 May meeting with regard to how data destruction will be monitored or transition arrangements will be implemented for recipients on the expiry of the National Health Service (Control of Patient Information Regulations) 2002 (COPI) regulations. NHS Digital advised that the special condition wording outlined in the briefing paper would be updated to reflect the current, more robust, agreed wording to cover the expiry of the COPI Notice. **Templated Application (CCG pseudonymised templated application) observations:** IGARD members noted that templated applications were about "managing" the COVID-19 emergency and not necessarily about supporting it. IGARD members reiterated their comment from the 28 May meeting that where data was supplied to a CCG there needs to be clarity that it is not already obtained by another route, as this would be contrary to the principles of data minimisation (NHS Digital DARS Standard 3: Data Minimisation). IGARD queried if DARS wished to raise this point about duplicate flows of GP data with PAG, to suggest that the RCGP or other appropriate body issues a communication to GP practices that GP data requests should be referred to NHS Digital. IGARD members noted a number of typos which would need to be amended including, but not limited to, ensuring correct use of 'practice'; to ensure COVID-19 was always capitalized; to ensure that acronyms were spelt out on first use i.e. DARS; to ensure that the correct acronym was being used in relation to GPES Data for Pandemic Planning & Research; and to finish the sentence under the heading 'onward sharing'. IGARD members noted that the paragraph under the heading 'onward sharing' should be revised to be clear that the data **cannot** be onwardly shared.

	IGARD suggested that clarification be sought from IG with regard to pseudonymised data being disseminated but using COPI as the legal basis (which related to identifiable confidential patient information). IGARD members noted that reference to '*appointment management*' should be removed since that could not be undertaken with pseudonymised data, but to retain reference to '*analysis of potential impact'* which could be undertaken with pseudonymised data. IGARD members reiterated their comment from the 28 May meeting that the extent of GP data needs to me more clearly specified: i.e. no free text, and that the CCG is receiving just coded data and that this should be clearly articulated in section 5 of the templated applications. IGARD noted the concerns of NHS Digital with regard to adding into a templated application a link to 'usual business rules' and that the information was available via the NHS Digital website. IGARD observed that since the templated application becomes the Data Sharing Agreement which contains contractual terms that NHS Digital can enforce, if required, it would be more expedient to make a clear narrative reference to the "usual business rules". IGARD members noted that the special condition in section 6 (Special Conditions) would be updated to reflect the current, more robust, agreed wording to cover the expiry of the COPI Notice.
2.2	<u>NIC-372269 University College London</u> **Background:** This was a verbal update to the materials presented to the COVID-19 response meeting on the 26 May 2020. The application was with regard to understanding the community incidence, symptom profiles and transmission of COVID-19 in relation to population movement and behaviour. The Virus Watch study aims to evaluate a number of approaches and which are likely to help inform NHS planning and the national public heath response. **IGARD Observations:** IGARD members noted that the materials they had reviewed at the COVID-19 response meeting on the 26 May had not stated General Data Protection Regulation (GDPR) consent as the GDPR legal basis, however the application for review today and the applicant's website clearly stated that the GDPR legal basis for this study was under article 6(1)(e) (consent) and 9(2)(a) of the GDPR. IGARD members noted that recruitment to the study had already begun and was currently using a patient information sheet (PIS) they had not previously had sight of, dated 15 June 2020, which explicitly stated consent as the GDPR legal basis for processing. IGARD members noted that the supporting documents they had reviewed at the 26 May COVID-19 response meeting had been dated either the 18 May or 21 May, however the documentation that was uploaded to the applicant's website and which had gained ethical approval were dated 26 May and 15 June 2020. It was also noted that when presented for review on the 26 May that section 7 (Approval Consideration) of the application stated that "*Ethics approval is not required because*", however the updated application presented today, stated in section 7 that a number of documents had had ethical approval and had subsequently been uplifted to June 2020 dates,

	but the ethics approval documentation had not be provided as part of the review, nor the revised consent and patient information sheets dated June 2020. IGARD suggested that the applicant may wish to review the Information Commissioner's Office (ICO) and the Health Regulatory Authority (HRA) websites for information on the suitability or otherwise of GDPR consent as a legal basis for processing. IGARD observed several aspects of the consent that may be troublesome if held to a GDPR consent standard, such as how participants could withdraw consent, noting that under GDPR consent the applicant could not continue to hold data for those that had withdrawn consent and the risk of possible coercion if entire households had to take part in the study. IGARD members noted the verbal update from NHS Digital that the applicant only wished to retain the data for 12 months, however SD1.2 'Children's patient information sheet (10-15 years) final' stated "…*we may do this for up for 5 years after you join the study…*' and SD1.2 'Adult participant information sheet final' stated "…*and for 5 years after the study has finished*…". Noting that it was not clear if this was 5 years from when they signed the consent forms or 5 years from the study ending, further clarity should be sought and the documentation updated to reflect the new information. In addition, SD2.1 'Adult consent form final' stated "…*information collected about me will be stored by UCL for at least 10 years*…" and to ensure this statement was compatible with NHS Digital's data sharing agreement. Noting that assent would be obtained where appropriate plus parental / guardian consent (a copy of this supporting document was not provided as part of the review) for those aged 15 and under, consideration should be given as to those children who would reach adulthood during the study and how the applicant would reconsent those adults, including how participants could withdraw from the study. IGARD members noted that at the time of consenting to be part of the study, the participant was given a summary patient information sheet, however it was not clear if the participant also received the full version, which gave further details about the study etc. IGARD members noted that SD4 'Study Protocol' noted "…*We will also seek to recruit Polish groups*…" and queried why this European nation in particular had been singled out. Noting that the "…*The lead householder needs to be able to read English to support other household members in survey completion*…" but that SD1.3 'Adult Participation Summary Sheet Final' noted "…*This participant information sheet is available in the following additional languages – Urdu, Bengali, Punjabi, Portuguese, French and Polish*…" queried how it all fitted together.
2.3	<u>NIC-381683-R6R6K University of Oxford (main route application)</u> **Background:** This was a verbal update to the application and supporting documentation presented to the COVID-19 response meeting on the 26 May 2020 with regard to five University of Oxford studies: three of which were observational and two of which were clinical trials, and 9 June 2020 (noting it had been listed under the applicant: Public Health England (PHE)). This application related to the three observational studies. NHS Digital noted that these studies have received Health Data Research UK (HDRUK) and NHS Digital prioritisation. PHE had commissioned the Royal College of General Practitioners (RCGP) Research Surveillance Centre (RSC) to incorporate the monitoring of COVID-19 into its virology surveillance scheme and a vital part of this work has been to monitor the number of suspected COVID-19 cases in the community in a timely way. The aim of the application was for RCGP

	RSC to conduct observational epidemiological studies to inform the national public health response to COVID-19 with three distinct workstreams of: COVID-19 surveillance; defining the characteristics of individuals with suspected novel COVID-19 and risk factors of developing the disease; and monitoring attendance, investigation, referral, and outcomes in Primary Care and recovering from COVID-19 lockdown. NHS Digital noted they were awaiting feedback from NHS Digital information governance (IG) on the applicant's reliance on the National Health Service (Control of Patient Information Regulations) 2002 (COPI) regulations and IGARD asked that when received this formed part of the suite of supporting documentation for this application and that it was uploaded as a statement of fact to the Customer Relationship Management (CRM) system. **IGARD Observations:** IGARD members queried why the application would go down the SIRO precedent and noted that for such a high-profile applicant / application that NHS Digital may also wish for the assurance of an independent review via the Thursday BAU IGARD meeting. IGARD members queried why the applicant was requesting data from 2009 onwards, since the application was with regard to the current COVID-19 pandemic, and suggested that this be clearly justified in section 5 (Purpose / Methods / Outputs) of the application as outlined in the NHS Digital DARS Standard 3: Data Minimisation. IGARD members noted the three Data Controllers listed as: PHE, University of Surrey and Royal College of General Practitioners (RCGP) and suggested that it be clearly articulated in section 5 the role and remit of each of the Data Controllers. IGARD were unclear as to why the University of Oxford was listed as at Data Processor and the applicant for this application. NHS Digital note that the lead professor was a substantive employee of both the University of Oxford and University of Surrey. IGARD suggested that a clear narrative be included in section 5 outlining the University of Oxford's role. IGARD members queried why the University of Oxford was not listed as a storage location and suggested that this be updated, if necessary. IGARD members reiterated their comment from the 9 June meeting with reference to opt-outs for the data collection by Apollo from practices, and it wasn't clear if this referred to national opt-outs, type 1 objections or more specific study opt-outs and that this should be clearly updated within relevant materials provided to the cohort and explained within the application. IGARD suggested that since it was not clear in section 5 of the application, the process of data flows into and out of the various Data Processors and NHS Digital, that this should be clearly articulated and that a data flow diagram be provided. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. It was also noted that the Research and Surveillance Centre information for patients on the RCGP website has not been updated since December 2017.
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.