Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 16 July 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:**
Dave Cronin	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics (Observer: items 2.1 to 2.4)
Karen Myers	IGARD Secretariat
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Paul Affleck noted professional links to Leeds Teaching Hospitals NHS Trust (NIC-170647-Z0B6H) but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 9th July 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	University Hospital Southampton NHS FT: The Distribution of Highly Sensitive Troponin in the Critically Unwell and Associated Mortality (Presenter: Louise Dunn) NIC-349889-Q7R7K **Application:** This was a new application for a one-off extract of pseudonymised Civil Registration data, for the purpose of a study aiming to assess whether high-sensitivity troponin taken in critical illness is a predictor of longer-term mortality. Troponin refers to a group of proteins that help regulate the contractions of the heart and skeletal muscles, high troponin levels can indicate a problem with the heart. The heart releases troponin into the blood following an injury, such as a heart attack. The results from these analyses will result in improvements in the way clinicians interpret high-sensitivity troponin levels but may also precipitate further studies to assess whether any medical interventions could alter the outcomes in at risk groups identified by this study. **Discussion:** IGARD noted the statement in section 5(a) (Objective for Processing) that *"The original study was funded by an unrestricted research grant from Beckman Coulter…"*, and asked that section 5(e) (Is the Purpose of this Application in Anyway Commercial?) was updated with a clear explanation that while the pharmaceutical company, Beckman Coulter had provided an unrestricted research grant, they were also a manufacturer of troponin assays. IGARD queried the references within the application to *"gender"* being requested, and advised that the Health Research Authority Confidentiality Advisory Group (HRA CAG) support stated that confidential patient information required was *"sex"* data; and asked that the datasets requested in the application aligned with the specific HRA CAG support. IGARD noted that the HRA CAG support stated that information about the study should be made publicly available; and in response to this, the applicant had provided confirmation to HRA CAG that the study information would be displayed on the Trust website. IGARD asked that for the purpose of transparency, the applicant's website was updated to ensure there was an easily accessible description of the study, and in accordance with the assurances provided by the applicant to HRA CAG, and which underlie the HRA CAG support for this study, that a special condition was inserted in section 6 (Special Conditions), stipulating that this update was made within three months of signing the Data Sharing Agreement (DSA). IGARD noted the HRA CAG recommendations in terms of public engagement and suggested that the applicant may wish to consider engaging with relevant interested patient and public groups, for example the British Heart Foundation or similar third sector organisations, to ensure reaching as wide an audience as possible. In addition, IGARD also noted that the study-specific privacy notice was difficult to locate, and asked that for transparency, the applicant ensured this was easily accessible online. IGARD queried how the identifying data and the pseudonymised data was being segregated, to avoid the data being re-identified, for example the two sets of data being split across separate databases; and asked that section 5(b) (Processing Activities) was updated with clarification of how the identifying data and the pseudonymised data were segregated by the applicant. IGARD also asked that a special condition was inserted in section 6, stating that there would be no data linkage between the identifiers and the pseudonymised data held by the Data Controller.

	IGARD suggested the applicant considers the potential mismatch between the datasets used, for example data accessed from NHS Digital versus data from clinical records, in respect of how the National Data Opt-Out is able to be applied at present. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(e) to provide a clear explanation that while Beckman Coulter has provided an unrestricted research grant, they are also a manufacturer of troponin assays. 2. To ensure that the datasets requested align with the specific HRA CAG support, for example 'sex' vs 'gender'. 3. To update the applicant's website to ensure there is an easily accessible description of the study (in accordance with the assurances provided by the applicant to HRA CAG and which underly the HRA CAG support for this study) and to insert a special condition in section 6, stipulating that this update is made within three months of signing the DSA. 4. To ensure that the study-specific privacy notice is easily accessible online. 5. To update section 5(b) to clarify how the identifying data and the pseudonymised data are segregated by the applicant. 6. To insert a special condition in section 6, stating that there will be no data linkage between the identifiers and the pseudonymised data held by the Data Controller. The following advice was given: 1. IGARD suggested that the applicant may wish to consider engaging with relevant interested patient and public groups, for example the British Heart Foundation or similar third sector organisations, to ensure reaching as wide an audience as possible. 2. IGARD suggested the applicant considers the potential mismatch between the datasets used, for example data accessed from NHS Digital versus data from clinical records, in respect of how the National Data Opt-Out is able to be applied at present.
2.2	<u>Medicines and Healthcare Products Regulatory Agency (MHRA): Clinical Practice Research Datalink (CPRD) R23 - Clinical Practice Research Datalink (CPRD) Routine Linkages Application (Presenter: Louise Dunn) NIC-15625-T8K6L</u> **Application:** This was an amendment application for NHS Digital to act as a trusted third party for data linkage, CPRD have requested that NHS Digital link CPRD data with Intensive Care National Audit and Research Centre (ICNARC) Case Mix Programme (CMP) data. The Clinical Practice Research Datalink (CPRD) is a centre of the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care (DHSC), which regulates medicines, medical devices and blood components for transfusion in the UK. The purpose of the amendment, is to support research questions that seek to study serious outcomes of disease involving admission to critical care or longer-term outcomes of interventions in intensive care. The data will allow studies which need information on risk factors, treatments or longer-term outcomes that are recorded in the primary care data as well as treatments and outcomes recorded in critical care. For instance, survival models can be developed to describe the association between key premorbid clinical factors (e.g. sociodemographics, comorbidities, prescribing, other clinical factors) and outcomes relating to critical care admission, critical care survival, and length of critical care stay. NHS Digital advised IGARD that this application had been presented at the IGARD – NHS Digital COVID-19 Response meetings, in terms of the release of the 'Second Generation Surveillance System' (SGSS) and the 'COVID-19 Hospitalisation in England Surveillance

	System' (CHESS); and confirmed that this had been done via The Health Service (Control of Patient Information) Regulations 2002 (COPI) legal basis and released through NHS Digital's Senior Information Risk Owner (SIRO) precedent. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 12th May, 19th May and the 26th May 2020; and the update from NHS Digital in respect of the SGSS and the CHESS data being released via the SIRO precedent. IGARD had a lengthy discussion on the breadth and scope of the complex application and agreed that the discussion for this application would be in respect of the ICNARC amendment only. IGARD also noted and commended the applicant for the Regulation 5 support for the requested amendment and noted that they were not relying on temporary COPI notice legislation. In respect of the SGSS and the CHESS data, IGARD noted the special condition in section 6 (Special Conditions) that stated this data *"cannot be included in research projects outside of the EEA"*, and asked that section 2(c) (Territory of Use), which stated the territory of use was *"worldwide"* was updated to state that the SGSS and CHESS data may not be accessed outside the EEA. IGARD discussed the sub-licence arrangements for the NHS Digital data, in particular that the pharmaceutical or other commercial companies would also sub-licence the data; and asked that section 5(e) (Is the Purpose of this Application in Anyway Commercial?) was updated to reflect these sub-licensing arrangements and further information of how the pharmaceutical or other commercial companies would benefit from the data to advance their commercial aims, and in line with NHS Digital's Data Access Request Service (DARS) Commercial Standard 5(e). In addition, IGARD noted that NHS Digital Information Governance (IG) advice had been sought by DARS and suggested uploading to NHS Digital's Customer Relationship Management (CRM) system, any IG advice relating to CPRD's sub-licensing arrangements as a future supporting document. IGARD noted the references in section 1 (Abstract) and section 5(a) to *"**consenting** GP practices"*, and asked that these were replaced to more accurately describe that they were *"**participating** GP practices"*, or similar. 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. IGARD briefly discussed the open issues with the overall application, and advised NHS Digital that these would require resolution for the renewal that was due in October 2020, and in addition, IGARD suggested that a meeting with NHS Digital and another external third-party body, to discuss the open issues, and before the application returns to IGARD in October 2020 should be considered. The immediate issues identified by IGARD, included, but were not limited to: the fundamental nature of the data being received by CPRD and then shared under sub-licence (e.g. identifying, pseudonymised, anonymised or anonymous); the inconsistency between the description of the data within the application and as described on the CPRD website; the reference to SGSS and CHESS data and the geographical limitations on their use; the ability of CPRD to rely on Reg 3 of COPI for sub-licensing and the significance of the limit to EEA and the issue of transparency for GP practice patients and the accuracy of the statements made within the relevant transparency materials.

	Noting that one IGARD member abstained from the recommendation to approve (still having concerns about the structural issues of the application previously identified), a further discussion was held between the IGARD members on the process for reaching a recommendation. IGARD agreed in accordance with the IGARD Terms of Reference, they would recommend for approval by way of a majority vote of 5 members, with 1-member abstaining. **ACTION:** IGARD suggested a meeting with NHS Digital and another external third-party body, to discuss the open issues, and before the application returns to IGARD in October 2020. **Outcome:** The application was recommended for approval by way of a majority vote of five, with one member abstaining, for the amendment to link CPRD data with ICNARC data only, and without prejudice to a number of open issues that should be addressed before it returns to IGARD for a full review. The following amendments were requested: 1. To update section 5(e) to reflect the use of the sub-licence of the NHS Digital data, for example, that pharmaceutical or other commercial companies will sub-licence the data and how they will benefit from the data to advance their commercial aims (NHS Digital Commercial Purpose Standard refers). 2. To update section 2(c) to reflect the special condition that SGSS and CHESS data may not be accessed outside the EEA. 3. To replace reference to "*consenting* GP practices" with "*participating* GP practices", or similar. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. 3. IGARD suggested uploading to NHS Digital's CRM system, any NHS Digital IG advice relating to CPRD's sub-licensing arrangements. The open issues for resolution by renewal include (but are not limited to): 1. The fundamental nature of the data received by CPRD and then shared under sub-licence (e.g. identifying, pseudonymised, anonymised or anonymous). 2. The inconsistency between the description of the data within the application and as described on the CPRD website. 3. Reference to SGSS and CHESS data and the geographical limitations on their use; the ability of CPRD to rely on Reg 3 of COPI for sub-licensing and the significance of the limit to EEA. 4. The issue of transparency for GP practice patients and the accuracy of the statements made within the relevant transparency materials.
2.3	<u>University Hospitals Bristol and Weston NHS Foundation Trust: The Sunflower Study (Presenter: Louise Dunn) NIC-170647-Z0B6H</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), Civil Registration, Diagnostic Imaging Dataset (DIDs) and Emergency Care Data Set (ECDS) data. The purpose is for a study which aims to provide the NHS with evidence as to whether testing for common bile duct (CBD) stones before gallbladder surgery is worthwhile or not in patients at low to moderate risk of having stones. Around 70,000 patients a year undergo gallbladder surgery. Gallbladder stones may pass from the gallbladder to the CBD

	where they may remain without symptoms, cause problems including pain, jaundice and acute pancreatitis, or they may pass spontaneously into the gut. **Discussion:** IGARD queried the Data Controller(s) and Data Processor(s) listed within the application, and noted that they differed from the information provided within the patient information material(s); and asked that the application was updated throughout to be clear on who the Data Controller(s) and Data Processor(s) were, and to ensure that all materials were aligned. IGARD noted the reference in section 1 (Abstract) and section 5(a) (Objective for Processing) to *"1 additional year of follow up",* and queried if this was, for example from the date of procedure or the calendar year, and asked that these references were updated with further clarity since the materials provided to the participant such as the Patient Information Sheet were not clear that data may be obtained for the participant prior to surgery. IGARD queried the information within the data minimisation column in section 3(b) (Additional Data Access Requested) that stated *"Please see Additional Production Details"* and asked that this was updated to remove this reference and to replace with a brief lay summary of the data minimisation activities. IGARD queried how the identifying data and the pseudonymised data was being segregated, to avoid the data being re-identified, for example the two sets of data being split across separate databases; and asked that section 5(b) (Processing Activities) was updated to clarify how the identifying data and the pseudonymised data were segregated by the applicant. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. In addition, IGARD noted that the Patient Information Sheet provided only included the website link to the generic privacy notice, and asked that this was updated to include a website link to the study-specific privacy notice. IGARD queried the two references in section 5(b) (Processing Activities) to *"18 months"* and noted that there was differentiating information for these references for example "*at least 18 months*" and "*up to 18 months*", and asked that this was updated to ensure the references were clearly aligned. IGARD noted the information provided in section 5(c) (Specific Outputs Expected) in relation to the wider dissemination activities, and asked if this could be updated to expand on this, including further details of what might be envisaged, taking into account the age range of the cohort group, and whether, for example, social media was referenced; and in addition that further details of the Study Management Group was also provided. IGARD suggested that the study website and any future patient consent materials were updated to confirm when the NHS Digital date would flow from. IGARD observed that the application and therefore the Data Sharing Agreement (DSA) prohibits remote access, and suggested that thought should be given to the activity taking place during the current pandemic, and how this aligned with the provisions of the DSA. **Outcome:** recommendation to approve subject to the following condition: 1. To update the application throughout and the patient information material(s) to be explicitly clear who the Data Controller(s) and Data Processor(s) are, and ensure that all materials are aligned. The following amendments were requested: 1. To update the reference in section 1 and section 5(a) to *"1 additional year of follow up"*, and to be clear when this will run from, for example, the date of procedure or the calendar year.

	2. To update the data minimisation column in section 3(b) to remove the reference to *"additional production details"* and replace with a brief lay summary. 3. To update section 5(b) to clarify how the identifying data and the pseudonymised data are segregated by the applicant. 4. To update the Patient Information Sheet to include a website link to the study-specific privacy notice. 5. To update section 5(b), to ensure the two references to *"18 months"* are clearly aligned. 6. To update section 5(c) to provide further information on the wider dissemination activities, including further details of what might be envisaged (noting the age range of the cohort group), and further details of the Study Management Group. The following advice was given: 1. IGARD suggested that the study website and any future patient consent materials are updated to confirm when the NHS Digital date will flow from. 2. IGARD observed that the application prohibits remote access, and thought should be given to the activity taking place, and how this aligns with the provisions of the DSA. It was agreed the condition would be approved OOC by IGARD Chair.
2.4	<u>London North West University Healthcare NHS Trust: Colonoscopic Surveillance for Familial Risk of Colorectal Cancer (Presenter: Kimberley Watson) NIC-148406-2YXPR</u> **Application:** This was an amendment application for the addition of Kings College London as a Data Controller. The purpose is for a long-running surveillance programme, with the aim of seeing if surveillance is successful in preventing cases of colorectal and other cancers. It also allows an assessment of whether there are other causes of death that occur more frequently than expected in the cohort. In addition to service evaluation, associated research is being undertaken with the following aims: 1) to ensure best practice in offering appropriate surveillance to individuals at increased risk of colorectal cancer due to a strong family history of colorectal cancer; 2) to quantify the risk of colorectal cancer associated with different family histories and individual characteristics including molecular genetic testing of patients' tumours and germline DNA; 3) To understand the natural history of colorectal neoplasia and effectiveness of colonoscopy in different groups. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD agreed that whilst the discussion would focus on the amendment in respect of adding Kings College London as a Data Controller, there were a number of issues that must be addressed by the renewal date of August 2020, and before its submission to IGARD for a full review. IGARD noted that there was a fixed historic cohort up to 2018, and queried if there were any plans to transition the members of this cohort to the consent model, noting that their understanding was that the Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support was time limited, and asked that confirmation of this was provided; and that if there were no such plans, that an explanation was provided as to why not. IGARD also noted that the continuation of the HRA CAG support was pending and the documentation provided as part of the review was dated 2018 and asked that written evidence was provided confirming that the HRA CAG support was continuing, such as evidence of the date the HRA CAG Annual Review was submitted. IGARD noted benefits of the study had been outlined in section 5(d) (Benefits) but asked that these were updated further to also reflect that reduction in colonoscopies also improved the patient experience.

	IGARD noted that section 3(c) (Patient Objections) stated that patient objections were applied, and asked that this was updated to correctly state that this only referred to the flow of any confidential data. IGARD queried if the information provided in section 5(a) (Objective for Processing), purpose 1, that the data was being used for non-research purposes, namely, direct clinical care was accurate, and asked that confirmation was provided; in light of IGARD's observation that the National Data Opt Out should **not** be applied to any data flow that was being used for the purpose of direct care. IGARD discussed the honorary contract for the Professor referred to in the application, and asked that a special condition was inserted in section 6 (Special Conditions) confirming that a contract for the Professor would be provided by the next renewal date and would meet NHS Digital's Data Access Request Service (DARS) usual standard for honorary contracts. IGARD noted that the next amendment of this agreement would be with regard to moving the clinical database location and Data Processor to King's College London and suggested that the applicant should notify the relevant Ethics Committee in advance of this move, as per process. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. In addition, IGARD suggested that the additional Data Controller, King's College London, revised and updated their privacy notice and that this was General Data Protection Regulation (GDPR) compliant. 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 The following amendments were requested and must be addressed by the renewal date of August 2020, and before its submission to IGARD for a full review: 1. On the understanding that the HRA CAG support is for a fixed historic cohort up to 2018, to provide confirmation if there are any plans to transition the fixed cohort members to a consent model, and if not, to provide explanation as to why not. 2. To provide written evidence confirming that the HRA CAG support is continuing, such as evidence of the date the HRA CAG Annual Review was submitted. 3. To update section 5(d) to reflect that reduction in colonoscopies improves the patient experience. 4. To update section 3(c) to refer to only the flow of confidential data. 5. To provide confirmation whether the statement in section 5(a), purpose 1, that the data is being used for non-research purposes, namely, direct clinical care is accurate. (IGARD observed that the National Data Opt-Out should not be applied to any data flow that will be used for direct care.). 6. To insert a special condition in section 6 confirming that a letter contract for the Professor will be provided by the next renewal date and meeting NHS Digital's DARS usual standard for honorary contracts. The following advice was given: 1. IGARD suggested that King's College London revise and update their privacy notice and that this is GDPR compliant. 2. IGARD suggested that the applicant should notify the relevant Ethics Committee in advance of the clinical database moving location.

	3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.5	<u>Office for National Statistics (ONS): Request for remote access to GPES data and linked GPES, HES (including APC, OP, A&E, critical care) and mortality data (Presenter: Dave Cronin) NIC-388794-Z9P3J</u> **Application:** This was a new application for identifiable GPES Data for Pandemic Planning and Research, Hospital Episode Statistics (HES) and Civil Registration data, for the purpose of research into the production of official statistics in respect of COVID-19. The results of the analysis will be used to inform members of the Scientific Emergency Group for emergencies (SAGE), Members of Parliament (MPs) and other government officials of the differing COVID-19 risk profiles experienced by UK citizens. This will enable the government to refine its policy response to the pandemic using the best evidence available. The analysis may also improve the public's understanding of the risk faced by individuals, leading to more informed personal decision making, and add to the growing body of literature being produced and evaluated by the global academic community. This application previously came to IGARD on the 9th July 2020 for advice, where IGARD made a number of observations and suggestions for further consideration. NHS Digital advised that further changes had been made to the application following the submission to IGARD for review, and an updated application was circulated to IGARD during the meeting. **Discussion:** IGARD noted the update from NHS Digital in relation to the further amendments in light of the urgency of the data, and thanked NHS Digital for the revised application to support the discussion. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 8th July 2020, and that notes from this meeting had been attached to the IGARD minutes from the 9th July 2020. IGARD queried the reference in section 5(a) to *"No 10"* and their view of the project being enabled, and queried who this was referring to for instance the Government, the Prime Minister etc, and asked that this reference was updated to either replace the reference with a specific Department or body with the power to request access to the NHS Digital data; or to remove the reference from the application. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD noted that within the applicant's privacy notice, there was a spreadsheet containing information of the data the applicant had access to, and asked that a special condition was inserted in section 6 (Special Condition), that the applicant would take all reasonable endeavours to include a description of the data in the excel spreadsheet within their privacy notice, before processing this data, and no later than one month of the Data Sharing Agreement (DSA) being signed. IGARD noted ONS' access arrangements, for example in relation to homeworking, and NHS Digital's requirement (if any) in light of the access within NHS Digital's data environment; and asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated to include confirmation that NHS Digital's Security Advisor had reviewed ONS' access arrangements and that they were content.

	IGARD queried why data was not being de-identified and linked by NHS Digital, and asked that an explanation was provided in section 1 outlining the pragmatic reasons for this. IGARD noted that one of the points raised previously was in relation to NHS Digital's locations being listed within section 1 and section 2 (Locations); and the explanation from NHS Digital was that this was consistent with other Data Access Environments (DAE) scenarios. IGARD asked that a further explanatory note was included in section 1 confirming this and for future reference. IGARD discussed how NHS Digital could improve transparency about access that was being granted to data within NHS Digital's Data Access Environments, for example links on NHS Digital's website to the relevant research websites; and suggested that NHS Digital may wish to consider what steps could be taken to improve transparency. 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 "*GPES*" acronym. **Application:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to either replace the reference to *"No.10"* with a specific Department or Body with the power to request access to this data; or to remove this reference. 2. To insert a special condition in section 6, that the applicant will take all reasonable endeavours to include a description of this data in the excel spreadsheet within their privacy notice, before processing this data, and no later than one month of the DSA being signed. 3. To update section 1 and section 5 to include confirmation that NHS Digital's Security Advisor has reviewed ONS' access arrangements and are content. 4. To include an explanation in section 1 of the pragmatic reasons as to why data is not being de-identified and linked by NHS Digital. 5. To include an explanatory note in section 1 as to why the NHS Digital location are not listed within section 1 and section 2, which is consistent with other DAE scenarios. 6. 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. The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider what steps they could take to help improve transparency about access that is being granted to data within NHS Digital's DAE.
3	<u>Returning Applications</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. • NIC-147788-X0G5L Derby Teaching Hospital NHS FT • NIC-190996-C4P8G The Royal Marsden NHS FT • NIC-06759-X5V7P University of York • NIC-328464-Y5Y8F University of Kent • NIC-321968-S4Q6L Cambridge University

	IGARD welcomed the five applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. Moving forward, IGARD agreed that COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.
4	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and 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 14th July can be found attached to these minutes as Appendix B. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
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 10/07/20

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-59873-D8C6G	University College London	18/06/2020	1. To provide justification of why the full date of death remains after pseudonymisation; what significance keeping this potential identifier in the data set this will bring to the outputs and what real world benefits will accrue to patients by doing so.	IGARD members	Quorum of IGARD members	None

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

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

- None 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, 14 July 2020

In attendance (IGARD Members):	Paul Affleck (Specialist Ethics Member)
	Kirsty Irvine (Lay Chair)
	Dr. Geoffrey Schrecker (Specialist GP Member)
In attendance (NHS Digital):	Garry Coleman (DARS – Item 2.2)
	Dave Cronin (DARS – Item 2.5)
	Louise Dunn (DARS – item 2.1 and 2.2)
	Liz Gaffney (DARS – Item 2.5)
	Fran Hancox (DARS – item 2.3 and 2.4)
	Karen Myers (IGARD Secretariat – Observer)
	Kimberley Watson (DARS – observer item 2.3 and 2.4)
	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-391837-M1P3Z Public Health England (PHE) **Background:** this was a verbal update to a potential new application from PHE regarding access to a number of datasets to understand how cardiovascular status has impacted on COVID-19 outcomes for patients. **IGARD Observations:** IGARD members welcomed the verbal update at this early stage. IGARD members suggested that since there was already in place a British Heart Foundation Trusted Research Environment (BHF TRE) to study cardiovascular disease in relation to COVID-19 that the applicant may wish to join the collaborators of that TRE. If joining the BHF TRE was not a viable option, noting that PHE had another application which was to receive the whole GPES Data for Pandemic Planning & Research dataset, that thought

	should be given as to whether this application was indeed a standalone application or whether it could be one of the projects under the other PHE overarching Data Sharing Agreement. If this was best designed as a standalone project, and a separate flow of data was to be disseminated, that section 5 be clear about the uniqueness of this particular project and why it could not be coordinated with other work using the same data, linking back to NHS Digital's DARS Standard for Data Minimisation. IGARD members suggested that the applicant carefully consider the questions to be answered before choosing between GPES Data for Pandemic Planning Research data and NHS Health Check data. These datasets offer differing detail and are collected in different contexts, so consideration should be given as to which would be more appropriate and whether they in fact required *both* datasets. IGARD looked forward to reviewing the application and relevant supporting documentation in due course.
2.2	NIC-374190-D0N1M Genomics England **Background:** This was a verbal update to the application and supporting documentation presented to the COVID-19 response meetings on the 28 April, 5 May, 12 May, 16 June and 23 June 2020, and the IGARD business as usual (BAU) meeting on Thursday 25 June when IGARD had deferred making a recommendation. **IGARD Observations:** IGARD members welcomed the verbal update from the Associate Director Data Access. NHS Digital noted that further work with Genomics England was being undertaken with regard to their consent materials. IGARD members welcomed the approach and offered to support Genomics England and NHS Digital outside of the BAU or COVID-19 response meetings.
2.3	NIC-390964-G8W3R Care Quality Commission (CQC) **Background:** This was a new application and supporting documents for Ipsos Market and Opinion Research International (MORI) to carry out research on behalf of the CQC and system partners to understand the experiences of patients who have been admitted to hospital with COVID-19, compared to those admitted for non-COVID-19 reasons. It aims to provide information at national, regional and integrated care system (ICS) level on how safe, effective, caring and responsive care has been. CQC will gain an understanding of people's experiences of hospital care through the pandemic which can be disaggregated to consider the views of people from different demographic backgrounds, region or ICS which will inform regulatory response and support to NHS acute trusts and wider ICS and in the event of a second spike can support better care experiences for patients. **IGARD Observations:** NHS Digital confirmed that the application had received NHS Digital prioritisation and was currently with Information Governance (IG) for review. IGARD members noted the particular statutory role of the CQC and asked that the application be clear throughout of how the processing, objectives and outputs aligned with the National Health Service (Control of Patient Information) Regulations 2002 (COPI) in response to a public health emergency. IGARD noted that a commercial organisation, Ipsos MORI, were handling confidential patient data and particular care was needed in recording the legal basis relied on and ensuring that the

	processing was within COPI scope. In particular, IGARD members suggested that the survey questions were carefully focused on the monitoring and managing of the COVID-19 response and did not stray into matters of more general interest. It was noted that the applicant was receiving a large one-off drop of pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) and Demographic Extract data at stage one before at stage two the applicant requesting the identifiable data for a created cohort, however IGARD members asked for a clear rationale for this two stage approach. IGARD members noted within section 3(c) (Patient Objections) reference to '*type 2 opt outs'* and suggested that this was updated to '*national data opt-outs*' and that it be clear that since COPI was being relied upon that national data opt-outs did not apply. In addition, once the wording had been updated, IGARD members suggested that the application be updated to reflect this change in wording. As an alternative approach, thought could be given to applying the National Data Opt-Out which may reduce the numbers of citizens being surprised to be contacted by Ipsos MORI. IGARD members queried the legal basis which allowed Text Local to send '*text messages*' to the cohort with the invitation to the survey (and reminders) with links to the survey and in addition to printed letters. IGARD members suggested that consideration be given as to whether Ipsos MORI should be considered a Data Controller particularly in light of the fact that they were part of the decision making process for cutting down the large dataset into a contactable cohort. In addition consideration should be given as to whether all Ipsos MORI's sub-contractors should be considered Data Processors. IGARD members suggested that it be made clear the that supporting document letters provided (SD4 *T1 mailing letter v4* and SD5 *T2 mailing letter v3*) be clearly identified as '*sample letters*' and to ensure that all reference to '*Trusts*' were removed. Since it was clear within the application and supporting documents that CQC wished to obtain views from people from different demographic backgrounds queried why the information was only being provided in English. To ensure accessibility, IGARD suggested that for those where English was not their first language that communication be provided in other languages and that information provided be clear as to how to obtain documentation in another language. With reference to the application IGARD members suggested a number of amendments including, but not limited to: • Remove any non-relevant aspects associated with NHS Digital's DARS standards such as '*no moral or ethical issues*'. • To remove or reword reference to deceased patients being '*informally or formally dead*'. • With reference to exclusions from the cohort these should be reconsidered to give a more nuanced view of the exclusions, including but not limited to, the blanket exclusion of obstetric and maternity service users and psychiatry patients. If, however, the reason for the exclusion was due to a separate workstream to engage with those excluded and severely affected by COVID-19, this should be clearly articulated in section 5. • To ensure specific engagement with key groups including, but not limited to, obstetrics and maternity service users and mental health patients' representative groups.

	• To ensure that in section 5d (benefits) the reference to magnitude of the impact relates to the benefits flowing from the purpose of the application, not the process involved. • To update section 8a to be clear that '*depersonalised data will be kept after that date, indefinitely*' is in fact anonymous data (aggregated data with small numbers suppressed). IGARD members queried why the application would go down the SIRO precedent and noted that for such a potentially repercussive application (for example citizens being surprised to be contacted by Ipsos MORI when they have registered an opt-out) that NHS Digital may also wish for the assurance of an independent review via a Thursday BAU IGARD meeting.
2.4	<u>NIC-389914-N9R8R Department of Health</u> **Background:** this was a new application from the Department of Health and Imperial College London for demographic data to flow to Ipsos Market and Opinion Research International (MORI) in order to support the REACT2 study (Real-time Assessment of Community Transmission 2) for study 5 which is a nationally representative zero prevalence study through self-administered lateral flow tests. The overall objective of REACT2 is to assess the acceptability and usability of a self-sampling and self-testing kit for COVID-19 and the feasibility of using such a kit at home as part of a large study in the community. **IGARD Observations:** IGARD members asked that the application be clear throughout how the processing and objectives fit under the National Health Service (Control of Patient Information) Regulations 2002 (COPI) in response to a public health emergency, noting that the commercial organisation Ipsos MORI were handling confidential data. IGARD members suggested that consideration be given as to whether Ipsos MORI should be considered a Data Controller particularly in light of the fact that they were part of the decision making process for cutting down the large dataset into a contactable cohort. In addition consideration should be given as to whether all Ipsos MORI's sub-contractors should be considered Data Processors. IGARD members noted in section 3(c) (Patient Objections) that the national data opt-out did not apply, but suggested that it be made clear that this is because of the COPI Regulations. As an alternative approach, thought could be given to applying the National Data Opt-Out which may reduce the numbers of citizens being surprised to be contacted by Ipsos MORI. Given Ipsos MORI's International Standards Organisation (ISO) recertification audit is due before the 5 August 2020, IGARD members suggested that a special condition be inserted in section 6 (Special Condition) that it was incumbent on the applicant to let NHS Digital know, should the ISO certification not be renewed. IGARD members noted reference in section 2(c) (Territory of Use) to '*England / Wales*' and suggested that since one of the Ipsos MORI processing locations was based in Germany that this be amended appropriately. IGARD members noted within SD4 (*MORI COVID19 Project 5 PIS*) reference to *'the initial invitation was sent to your address after it was randomly selected…*' and SD6 (*Study 5 testing antibody individual invitation letter v1.6*) reference to '*you have been chosen at random from the NHS patient list in England…*' and suggested that due to the processing being undertaken

	with the data within a set of parameters, people were not being 'randomly' selected and suggested the language be updated. IGARD members noted within SD8 (*Antibody privacy policy v3.1*) reference to 'Imperial College London request your consent to link the study data to other health information that the NHS holds about you…' however the consent form provided as part of the review (SD5 – *REACT2 Study 5 Consent v1.0*) did not reference linkage and suggested that this document was updated to accurately reflect any proposed linkage being undertaken as part of this study. IGARD members queried why the application would go down the SIRO precedent and noted that for potentially repercussive application that NHS Digital may also wish for the assurance of an independent review via a Thursday BAU IGARD meeting.
2.5	<u>NIC-388794-Z9P3J – Office for National Statistics (ONS)</u> **Background:** This was a verbal update to the application which had been presented to the business as usual IGARD meeting on Thursday, 9 July and was to be re-presented to the BAU IGARD on Thursday, 16 July 2020. **IGARD Observations:** IGARD noted that this application had been presented to IGARD BAU on Thursday, 9 July for advice and that it was to be presented at this week's BAU meeting following a review by the Profession Advisory Group (PAG) on Wednesday, with a copy of their minute extract appended to IGARD's published minutes. IGARD members noted the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday, but a follow up to the points raised at last week's IGARD BAU meeting and they thanked NHS Digital for their verbal update.
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.