

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 22 April 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	Position:
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Vicky Byrne-Watts	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics and Deputy Caldicott Guardian (Observer: items 1, 3.1 - 3.4)
Nicola Jennings	Data Access Request Service (DARS) (Observer: items 1, 3.1 - 3.4)
Dickie Langley	Privacy, Transparency and Ethics
Karen Myers	IGARD Secretariat
Charlotte Skinner	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	Declaration of interests:
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	<p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19.</p> <p>Nicola Fear noted a professional link to King's College London [NIC-272253-P9X9Y] and although she did not have a specific connection with the application, advised that she did know the staff involved, and was aware of discussions that had taken place with members of the team, in respect of data storage for this application. It was agreed that as IGARD were only providing advice and not a formal recommendation, that this did not preclude Nicola from taking part in the discussions about this application.</p> <p>Nicola Fear noted that as part of her role at King's College London, she used the Clinical Record Interactive Search system (CRIS) data [NIC-408171-X7F8W] from the South London and Maudsley NHS Foundation Trust (SLaM), however she did not use data from Camden & Islington NHS Foundation Trust (C&I), and it was agreed that this was not a conflict of interest.</p> <p>Maria Clark noted a professional link with the British Medical Association (BMA) (NIC-344271-Q5X0S), but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 15th April 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	Data Applications
2.1	<p><u>University College London (UCL): Creating synthetic data for health research (Presenter: Catherine Day) NIC-419453-G3G1G-v0.4</u></p> <p>Application: This was a new application requesting permission to process Hospital Episode Statistics (HES) Admitted Patient Care (APC) data held under a separate Data Sharing Agreement (DSA) (NIC-393510-D6H1D).</p> <p>The purpose is to evaluate methods for creating 'synthetic' datasets for health research, by creating artificial datasets that 'look' like the original data source but that do not contain information on any real individuals. If such datasets can be created, synthetic data could be used by researchers to understand the structure of the data, develop data cleaning protocols, codes and algorithms, and test out methods. Final analyses could then be conducted once approvals are in place (in secure settings) or, alternatively, by the data providers.</p> <p>The data will be used to evaluate three synthetic data generators, Synthpop, Simulacrum and Jomo, in terms of how well they can create synthetic datasets.</p> <p>Discussion: IGARD noted that the purpose of the application was to process data held under a separate DSA (NIC-393510-D6H1D), and asked that section 1 (Abstract) was updated, with a brief extract from the master / overarching DSA, which clearly showed the basis for the data being reused in this application; and that a copy of that DSA was provided as a supporting document.</p> <p>IGARD noted within section 5(e) (Is the Purpose of this Application in Anyway Commercial) that the application was deemed as not being commercial, however IGARD queried if this was correct, in light of (inter alia) the reference in section 5(d) (Benefits) to UCL offering workshops</p>

on the synthetic data. IGARD asked, noting the [NHS Digital DARS Standard for Commercial Purpose](#), that in respect of any potential commercial element, present now, or that may be derived directly or indirectly from the data in the future, that section 5(a) (Objective for Processing) was updated to clarify any anticipated commercial nature or intention to monetise / generate income for example through charging for attendance at workshops; or, if there was no commercial element, section 5(a) was updated to clearly state this.

In addition, IGARD asked that if there was a commercial element, that section 5(e) was updated to reflect this, and in line with the [NHS Digital DARS Standard for Commercial Purpose](#).

IGARD noted that Article 6(1)(e) of the UK General Data Protection Regulation (GDPR) was the legal basis cited for the study, however queried if, pending the facts in respect of the commercialisation of the work, whether Legitimate Interest was the appropriate legal basis for some aspects of the work and that section 1 should be updated as appropriate.

IGARD queried the description of the Public Task legal basis in section 1 and section 5 (Purpose / Methods / Outputs) and noted that this did not align with the UCL description in other applications seen by IGARD, and asked that this was reviewed and updated to ensure this reflected the usual description of Public Task.

IGARD noted that they had not received a copy of the overarching master list of applicant legal bases from NHS Digital which provided the narrative for each applicant (which is to be referenced in section 1), and asked that this was provided, and that reference to the list was made in section 1.

IGARD noted that section 5 contained minimal information on the business / operating model for Simulacrum, Synthpop and Jomo, and asked that this part of the application was updated to provide a further explanation of their business and / or operating model for transparency.

IGARD noted the novel use of health data outlined for the study, and asked that, as section 5(a) formed part of the public-facing release register, that this was updated to provide some illustrative examples of “*synthetic data*” and, if possible, to include a link to a reliable public resource that further defined the concept.

IGARD noted that section 5(b) (Processing Activities) contained a very brief overview of how the processing would work, and advised that the information provided was not very clear, and asked that this was updated with a further explanation; would all the variables, for example sex, be synthetic.

IGARD queried a number of individuals referenced in supporting document 1, the funding letter from the Economic and Social Research Council, dated the 15th December 2020, and asked that confirmation was provided as to whether they were employees of UCL, noting that they were not referred to in the application; and if not, asked that section 5 was updated, with a brief explanation of the involvement of the various organisations employing the individuals.

In addition, IGARD also asked that for transparency and future reference, a statement was provided in section 5, that those any other organisations included in the project were **not** considered joint Data Controllers and / or Data Processors.

IGARD noted the outputs outlined in section 5(c) (Specific Outputs Expected), and queried if any of the outputs were to determine if there were equality impact issues, and if, for example, there was a risk of structural bias; and asked that this was updated to clarify this point, and if the outputs would include an Equality Impact Assessment (EQIA); or that an explanation was provided, as to why this was not required and was not considered a risk.

IGARD noted the reference in section 5(c) to “...*aggregate level data with small numbers suppressed*...”; and asked that this was reviewed, and either updated with additional supporting information (in light of the nature of the synthetic outputs) or removed if deemed not necessary.

IGARD noted a number of acronyms in section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example, “*IMD*” and “*DfE*”.

Outcome: recommendation to approve subject to the following condition:

1. In respect of any potential commercial element present now or that may be derived directly or indirectly from the data in the future (noting the wide scope of NHS Digital DARS Standard for Commercial Purpose):
 - a) To update section 5(a) to clarify any anticipated commercial nature or intention to monetise / generate income, for example, by charging for workshops; or
 - b) If there is no commercial element, to clearly state this; and
 - c) To update section 5(e) to reflect any commercial aspects and in line with the NHS Digital DARS Standard for Commercial Purpose.

The following amendments were requested:

1. In respect of the legal basis:
 - a) To update section 1 and section 5 to ensure the description of the public task legal basis reflects the usual UCL description.
 - b) Pending the facts around the commercialisation of the work, whether Legitimate Interest is an appropriate legal basis for some aspects of the work.
 - c) NHS Digital, to provide a copy of the overarching master list of applicant legal bases and make reference to this in section 1.
2. To update section 5 to provide a further explanation of the business/operating model for Simulacrum, Synthpop and Jomo.
3. Noting that this is a public-facing release register and a novel use of health data, to update section 5(a) to provide some illustrative examples of “*synthetic data*” and, if possible, a link to a reliable public resource that further defines the concept.
4. To amend section 5 to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, for example, “*IMD*” and “*DfE*”.
5. In respect of the individuals mentioned in supporting document 1 to confirm that they are employees of UCL, if not:
 - a) To update section 5 with a brief explanation of the involvement of the various organisations employing the individuals.
 - b) To provide a statement in section 5 that any other organisations included in the project are **not** considered joint Data Controllers and / or Data Processors.
6. To update section 5(b) with a further explanation of how the processing will work, for example, will **all** the variables (e.g. sex) be synthetic.
7. To amend section 5(c) to clarify if the outputs will include an EQIA and if there is a risk of structural bias; or to provide an explanation as to why this is not required and not a risk.
8. To review the reference in section 5(c) to “...*aggregate level data with small numbers suppressed*...”; and either update with additional supporting information in light of the nature of the synthetic outputs or remove if deemed not necessary.

	<p>9. To update section 1 with a brief extract from the master / overarching DSA, which clearly shows the basis for the data being reused in this application; and to provide a copy of that DSA as a supporting document.</p> <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members.</p>
<p>3.2</p>	<p><u>NHS England (Quarry House): NHS England - Infections & Antimicrobial Resistance (AMR) Trusted Research Environment (Presenter: Kimberley Watson) NIC-448252-L2R6Q-v0.2</u></p> <p>Application: This was a new application for pseudonymised Civil Registration (deaths) data, Community Services Data Set (CSDS), Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatients, and Medicines dispensed in Primary Care (NHSBSA data); within the Infections & Antimicrobial Resistance (AMR) Trusted Research Environment.</p> <p>The World Health Organization (WHO) has declared that Antimicrobial Resistance (AMR) is one of the top 10 global public health threats facing humanity; as a result, in January 2019 the UK Government published a 5 Year UK Antimicrobial Resistance (AMR) National Action Plan (NAP) alongside a UK AMR 20 Year Vision Paper.</p> <p>The purpose of this application is for the post-discovery phase of the AMR programme, which will enable sufficient understanding of the data to shape development of the future operating model.</p> <p>The AMR programme is to deliver on a number of ambitions set out in the 5 Year NAP, which include, 1) halve the number of healthcare-associated Gram-negative Bloodstream Infections, delivering a 25% reduction by 2021- 2022 and the full 50% by 2023-2024; 2) reduce the number of specific drug-resistant infections in people by 10% by 2025; 3) reduce UK antimicrobial use in humans by 15% by 2024; and 4) reduce community antimicrobial use by 25% by 2024</p> <p>NHS Digital advised IGARD that the application had been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 21st April 2021 (please see Appendix B); and that PAG were not currently supportive of the GDPPR data flowing, due to there being no clear legal basis; and that until the queries / concerns raised by PAG had been addressed, the application would need to be updated to remove references to the GDPPR data.</p> <p>Discussion: IGARD noted that this application had also been reviewed by PAG on the 21st April 2021, and in addition to the notes provided, noted the verbal update from NHS Digital, in respect of PAG confirming that they were not supportive of the GDPPR data flowing since the application was not for COVID-19 purposes. IGARD advised that they supported PAG's concerns that there was no legal basis for the GDPPR data to flow and supported the relevant updates to the application to remove all references to the GDPPR data.</p> <p>IGARD noted that Electronic Prescribing and Medicines Administration (EPMA) data in Secondary Care for COVID-19 data was also included in this application, noted that this was for COVID-19 purposes only and the absence of a stated COVID-19 purpose in the application, IGARD suggested that this would need removing from the application and that the application be updated to remove all references to EPMA data.</p> <p>In addition, IGARD suggested to NHS Digital, that this application may be a suitable candidate for the GP beta dataflow, which was discussed at the IGARD meeting on the 15th April 2021.</p> <p>IGARD noted the rich source of data flowing under this application, and queried why there was no data minimisation within each of the datasets requested, for example, why were the fields</p>

not minimised to just those drugs related to AMR, and as set out in [NHS Digital's DARS Standard for Data Minimisation](#). IGARD asked that section 3 (Datasets Held / Requested) and section 5 (Purpose / Methods / Outputs) were updated, with a written justification, and in line with the [NHS Digital DARS Standard for Data Minimisation](#).

In addition, IGARD queried why **all** medical conditions within HES were being requested, for example, cardiovascular / erectile dysfunction etc; and not just those conditions relevant to AMR; and asked that a written justification was also provided in section 3 and section 5 clarifying this point.

IGARD noted that Civil Registration (death) data had been requested, and highlighted that where this specific data was flowing, that NHS Digital would review on a case-by-case basis, to determine if there was an increased risk of identification. IGARD agreed that, in this particular case, there was less risk due to NHS Digital undertaking the linkage. IGARD asked that section 1 (Abstract) was updated confirming that the flow of date of death data was in line with NHS Digital's policy assessment and would not increase the likelihood of re-identification of data subjects, in light of the data flowing for the entire population.

IGARD noted the reference in section 3(b) (Additional Data Access Requested) to the UK General Data Protection Regulation (GDPR) legal basis for the Civil Registration (death) data, and as this does not apply to deceased individuals, asked that this was removed.

IGARD noted in section 3(b) (Additional Data Access Requested) reference to the "*ordnance survey (OS) grid reference*". IGARD also noted that the Ordnance survey grid reference would flow to the TRE for HES Outpatients, and asked that section 5(a) (Objective for Processing) was updated with a justification for this. In addition, IGARD also asked that NHS Digital clarify whether the Ordnance survey grid reference, in addition to the other rich sources of data requested, impacted on the pseudonymised status of the HES Outpatients data.

IGARD noted the references throughout the application to "*NHSE/I*" (NHS England and NHS Improvement) and specifically noted that section 5(a) stated that "*NHSE/I*" were the Data Controller. IGARD queried if the entities that form NHS Improvement (Monitor and NHS Trust Development Authority) were joint Data Controllers alongside NHS England and were advised by NHS Digital that NHS England were the sole Data Controller. IGARD noted the update from NHS Digital, and asked that the application was updated throughout to ensure that it accurately reflected that NHS England was the *sole* Data Controller and that all references to "*NHSE/I*" were updated to "*NHSE*"

IGARD also asked that the application was updated to remove **all** references to "*NHSE/I*", for example "*NHSE/I analysts*", to avoid any confusion as to the roles and responsibilities of the various legal entities.

In addition, IGARD noted the statement in section 5(b) (Processing Activities) that "*NHSE/ substantive employees are only able to access the datasets detailed within this agreement.*", and asked that further clarification was provided on this, for example, is this within the TRE; and also asked that a special condition was inserted in section 6 (Special Conditions), that **only** substantive employees of NHS England can access the NHS Digital data within the TRE.

IGARD noted the storage location referenced in section 2(b) (Storage Location(s)) for NHS Digital's TRE, and asked that this was reviewed and amended if appropriate, to reflect the correct address, noting that NHS Digital had moved premises in Leeds from the 1st April 2021.

IGARD queried the statement in section 5(a) that every year in England, "*GPs prescribe 33.7 million courses of antibiotics to patients with **bloodstream infections**...*", and asked that this

	<p>was reviewed, and amended if necessary, for example, was this figure related specifically to patients with bloodstream infections, or should this in fact refer to all antibiotic prescriptions.</p> <p>IGARD noted the outputs in section 5(b) that <i>“NHS Digital developers will collaborate with NHSEI registered users to produce static visualisations of the data, which will be shared with AMR programme stakeholders in order to demonstrate the continuing value of the work being undertaken.”</i>; and asked that this was moved to correctly sit in section 5(c) (Specific Outputs Expected).</p> <p>In addition, IGARD also noted that the outputs already stated would enable more robust stakeholder engagement in term of developing next steps, and asked that section 5(c) was updated to reflect this as an output.</p> <p>IGARD noted that the ultimate aim of the overarching project was to address the global problem of antibiotic resistance and facilitate clear communication and reassurance to the public on the use or non-use of antibiotics. IGARD asked that section 5(d) (Benefits) was updated to clearly reflect this.</p> <p>IGARD advised, given the very large volumes of data requested, that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent.</p> <p>Separate to this application, IGARD advised they would welcome a briefing from NHS Digital’s TRE Data Minimisation Team to understand NHS Digital’s policy position and further their own learning and development.</p> <p>ACTION: IGARD would welcome a briefing from the TRE Data Minimisation Team to understand NHS Digital’s policy position on data minimisation in TREs.</p> <p>Outcome: IGARD do not recommended for approval the flow of GPPR and EPMA datasets, and were in agreement with PAG’s assessment that there was no legal basis to use the GPPR data, for the purposes outlined in this DSA.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of the data minimisation and in line with the NHS Digital DARS Standard for Data Minimisation: <ol style="list-style-type: none"> a) To provide a written justification in section 3 and section 5, as to why there is no data minimisation within each of the datasets requested, for example, why are the fields not minimised to just those drugs relating to AMR. b) To provide a written justification why all conditions within HES are being requested, and not just those conditions relevant to AMR. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the application throughout to remove references to the EPMA and GPPR data. 2. To update the application throughout to ensure it accurately reflects that NHS England is the <i>sole</i> Data Controller. 3. To update the application throughout to remove all references to <i>“NHSE/I”</i>, for example <i>“NHSE/I analysts”</i>. 4. To provide further clarification in section 5 to the statement that NHSE/I employees are only able to access the datasets, for example, is this within the TRE. 5. To insert a special condition in section 6, that only substantive employees of NHS England can access the NHS Digital data within the TRE.
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	<ol style="list-style-type: none"> 6. To review the NHS Digital TRE storage location in section 2(b) and amend if appropriate. 7. In respect of the Civil Registration (death) data flowing: <ol style="list-style-type: none"> a) To remove the reference in section 3(b) to the UK GDPR legal basis, as this does not apply to deceased individuals. b) NHS Digital to confirm in section 1 that the flow of date of death data is in line with NHS Digital's policy assessment and will not increase the likelihood of re-identification of data subjects, in light of the data flowing for the entire population. 8. In respect of the Ordnance survey grid reference: <ol style="list-style-type: none"> a) To update section 5(a) to provide justification for the Ordnance survey grid reference flowing to the TRE. b) NHS Digital to clarify whether the Ordnance Survey grid reference in addition to the other rich source of data requested, impacts on the pseudonymised status of the data. 9. To review the statement in section 5(a) to "<i>GPs prescribe 33.7 million course of antibiotics to patients with bloodstream infections...</i>", and amend if necessary. 10. To update section 5(b) to remove the reference to "<i>...produce static visualisations of the data...</i>", and move this output to section 5(c). 11. To update section 5(c) to reflect that the outputs will enable more robust stakeholder engagement in term of developing next steps. 12. To update section 5(d) to reflect the ultimate aims of the overarching project, namely, to address the global problem of antibiotic resistance and facilitate clear communication and reassurance to the public on the use or non-use of antibiotics. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD would welcome a briefing from the TRE Data Minimisation Team to understand NHS Digital's policy position. 2. IGARD suggested that this application would be a highly suitable candidate for the GP beta dataflow. 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, including the SIRO Precedent. <p>It was agreed the condition would be approved out of committee (OOC) by IGARD members.</p>
3.3	<p><u>Imperial College London: How can NCS healthcare data be connected with wastewater surveillance of COVID-19 in a privacy-preserving fashion to inform epidemiological models and democratise data access? (Presenter: Kimberley Watson) NIC-435753-D4J0Y-v0.4</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES) Admitted Patient Care (APC) data and Secondary User Service (SUS) Plus - APC (beta version). The data will be disseminated to the Office for National Statistics (ONS) and Imperial College London who will access the data via the ONS Secure Research Service (SRS).</p> <p>To protect communities, there is a need to find out how many people have COVID-19, and who they might infect. Some people never feel ill when they are infected with the virus, and may unknowingly pass it on to their families. Samples of sewage can be taken to measure the amount of genetic material it contains, which allows an estimation of how many people in the community are infected.</p>

The purpose is for the National Core Studies (NCS), to develop the methods required to link healthcare records to wastewater catchment areas; to generate data products that can be shared with researchers working on wastewater-based epidemiology; and, to calibrate wastewater-based epidemiological models and better predict the pandemic.

NHS Digital advised IGARD that the applicant had local ethics approval, however had applied for Research Ethics Committee (REC) ethical approval for this study from the Health Research Authority (HRA) and were currently awaiting the outcome of this.

Discussion: IGARD welcomed the application and noted the innovative use of the data requested and commended the applicant for the efforts outlined to share the outputs of the study.

IGARD noted the verbal update from NHS Digital in respect of the requisite ethical support, and asked that in line with the [NHS Digital DARS Standard for Ethical Approval](#), written confirmation was provided that HRA ethical support was in place; and that this was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD noted the special condition in section 6 (Special Conditions) that stated *"No data will flow under this agreement until **full** Research Ethics Committee (REC) Ethical approval has been gained..."*, and asked that this was updated to remove reference to *"full"* and replace with *"HRA"*.

IGARD noted that they had not received a copy of the overarching master list of applicant legal bases from NHS Digital which provided the narrative for each applicant (a reference to which is to be included in section 1), and asked that this was provided, and that reference to the list was made in section 1.

IGARD noted the references throughout the application to the *"Office of National Statistics"* (ONS), and asked the application was updated where relevant to ensure that ONS was referenced correctly as the Office **for** National Statistics.

IGARD queried the Imperial College London (ICL) storage location referenced in section 2(b) (Storage Location(s)), and noting that this was an ONS application and that data would be stored at ONS, asked for further clarity as to what data was being stored at ICL, and to update section 2(b) to reflect the factual scenario.

IGARD noted that Secondary User Service (SUS) Plus data had been requested, and queried if the proposed use of that data was within the permitted scope of the beta version of the dataset; and asked that further confirmation was provided.

IGARD queried the reference in section 5(a) (Objective for Processing) to the applicant having *"requested"* healthcare data pertaining to COVID-19 related symptoms, tests and hospital admissions, and, noting that the datasets requested from NHS Digital do not, in fact, contain any 'testing data', asked that if the applicant was accessing testing data within the ONS TRE, that section 5 (Purpose / Methods / Outputs) was updated, to make reference to the fact that this data would be linked with NHS Digital data. If the applicant was not accessing testing data within the ONS TRE, IGARD suggested that the applicant may wish to consider requesting testing data from NHS Digital, and that the requisite updates should be made to the application as appropriate.

IGARD noted that section 5 stated that there was no data linkage, however, asked that this was updated to clearly explain the linkage of NHS Digital data with the ONS data.

IGARD queried the statement in section 5(a) that *"All healthcare records will be anonymised by the Office of National Statistics (ONS) before they are ingested into a TRE..."*, and asked

<p>this was updated to be clear when the anonymisation was taking place; and that if further linkage was happening, to clearly explain how this would happen, since the data was anonymised.</p> <p>IGARD also queried what data and at what point, the NHS Digital data would be linked to the water sewage data, noting that this was not clear within the application, and asked that section 5 was updated with further clarification of this, and to confirm if this was before anonymisation.</p> <p>IGARD noted the statement in section 3(c) (Patient Objections) <i>“Data disseminated under the COPI Powers does not uphold patient objections.”</i>, and asked that this was updated to remove the current wording, and to instead make reference to statutory exemption.</p> <p>IGARD noted the references to <i>“Researchers”</i> in section 5(b) (Processing Activities) and asked that this was updated to clarify that this is referring to <i>“ICL Researchers”</i>, as is referenced in section 5(a).</p> <p>IGARD queried the references in section 5(c) (Specific Outputs Expected) to members of the public being involved in the research, and asked that this was updated to clarify that participants would be informed of the research rather than involved, since it was clear in the supporting documents provided that their involvement will be alongside the main study and not directly inform it.</p> <p>Noting that the patient and public involvement and engagement (PPIE) was running alongside this research, and would not inform its design, IGARD noted that ideally PPIE should be set up at the earliest opportunity so patients or other people with relevant experience contribute to how research is designed and conducted (see Health Research Authority advice at https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/)</p> <p>Outcome: recommendation to approve subject to the following condition(s)</p> <ol style="list-style-type: none"> 1. In respect of the requisite ethical support and in line with the NHS Digital DARS Standard for Ethical Approval: <ol style="list-style-type: none"> a) To provide written confirmation that HRA ethical support is in place. b) To upload the written confirmation to NHS Digital’s CRM system. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. NHS Digital, to provide a copy of the overarching master list of applicant legal bases. 2. To update the application where relevant to ensure that ONS is referenced correctly as the Office for National Statistics. 3. To clarify what data is being stored at ICL, and update section 2(b) to reflect the factual scenario. 4. In respect of the SUS Plus data requested to provide confirmation that the proposed use of the SUS Plus data is within the permitted scope of the beta version of the dataset. 5. In respect of COVID-19 testing data which the applicant notes they have <i>“requested”</i> and noting that the datasets requested do not, in fact, contain any testing data: <ol style="list-style-type: none"> a) If the applicant is accessing testing data within the ONS TRE, to make reference to the fact that this data will be linked with NHS Digital data within section 5. b) If the applicant is not accessing testing data within the ONS TRE, the applicant may wish to consider requesting testing data from NHS Digital, and the requisite updates should be made to the application as appropriate. 6. To clearly explain in section 5 the linkage with the ONS data. 7. To update section 3(c) to remove the current wording, and to instead make reference to statutory exemption.
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	<ol style="list-style-type: none"> 8. To update section 5(a) to be clear when the anonymisation is taking place, and if further linkage is happening, to clearly explain how this will happen, since the data is anonymised. 9. To clarify in section 5 what data and at what point, the NHS digital data will be linked to the water sewage data and is this before anonymisation. 10. To update section 5(b) to clarify that the “<i>Researchers</i>” are ICL Researchers. 11. To clarify in section 5(c) that participants will be informed of the research rather than involved. 12. To update the special condition in section 6, to remove reference to “<i>full</i>” and replace with “<i>HRA</i>”. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD noted that the PPIE is running alongside this research and will not inform its design. IGARD suggested that ideally PPIE was set up at the earliest opportunity so patients or other people with relevant experience contribute to how research is designed and conducted (see Health Research Authority advice at https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/) <p>It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.</p>
3.4	<p><u>University College London (UCL): Camden & Islington Clinical Record Interactive Search (CRIS) Linkage with HES/Mortality Data (Presenter: Charlotte Skinner) NIC-408171-X7F8W-v0.12</u></p> <p>Application: This was a new application for pseudonymised Civil Registration (Deaths) data, Demographics data, Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care and HES Outpatients data.</p> <p>The purpose of this application is to link HES and Mortality data with the Camden and Islington NHS Foundation Trust (C&I) Clinical Record Interactive Search (CRIS) Research Database for the purpose of research. The research resource would be used for research projects aiming to investigate physical health outcomes (including mortality) and receipt of health care in people with severe mental illness (SMI) attending secondary mental health care services provided by C&I.</p> <p>The proposed linkage would significantly increase high quality research outputs that examine the interface between mental and physical health.</p> <p>Discussion: IGARD noted and commended NHS Digital on quality of the information provided in section 1 (Abstract), which provides historical and additional background information which supported the review of the application by Members.</p> <p>IGARD confirmed that they were of the view that the s251 support provided an appropriate legal gateway to support the processing outlined in the application.</p> <p>IGARD noted the references in section 1 and section 5(a) (Objective for Processing) to University College London (UCL) being a “<i>research partner</i>”, and that they were also involved in the development and operation of the C&I database. IGARD queried if they should be considered a joint Data Controller, citing NHS Digital’s DARS Standard for Data Controllers. NHS Digital confirmed that UCL was not a joint Data Controller, and that their role was to provide management / administrative support to the database, rather than the data. IGARD noted the verbal update from NHS Digital, and asked that written confirmation was provided that UCL was not considered a joint Data Controller.</p>

IGARD queried the content of supporting document 5, the Camden and Islington NHS Foundation Trust honorary contract for researchers template, in particular the fact that it would only be signed by the user and not the employer of the individual to whom the contract relates to. IGARD asked that in line with [NHS Digital's DARS standard – Processing Activities](#), for further detail of what contractual arrangements were in place to protect the data when accessed by non-substantive employees, for example, counter signatory by the home research institution and / or employer on relevant honorary contracts.

IGARD noted a reference in section 5(a) to UCL Master of Science (MSc) and Doctor of Philosophy (PhD) students, and queried what the supervision arrangements were for the students, and were advised by NHS Digital that honorary contracts were in place. IGARD noted the verbal update from NHS Digital, and asked that written confirmation was provided that MSc and PhD students from UCL were covered by the honorary contract arrangements and that they also provided the appropriate coverage for a student.

In addition, IGARD noted that there were references in supporting document 5 to the “*Data Protection Act 1998*” (DPA 1998), and asked that, since this was now out of date, the references were removed and updated as appropriate to reflect the current legislation.

IGARD noted the reference in section 5(a) to the data being anonymised, and queried if this was correct, noting that section 3(b) (Additional Data Access Requested) stated the data was pseudonymised; and were advised by NHS Digital that it was pseudonymised and that the reference in section 5(a) was an error. IGARD noted the verbal update from NHS Digital and asked that section 5(a) was updated, to change the reference from “*anonymised*” to “*pseudonymised*”. In addition, IGARD noted that supporting document 7, the C&I Research Database Oversight Committee also referred to “*anonymised*” data, and suggested this was also updated to correctly refer to *pseudonymised* data.

IGARD noted the references throughout section 5 (Purpose / Methods / Outputs) to “*mental disorder*”, and asked that section 5 was updated, with an alternative, and more sensitive term, such as “*mental health condition*”.

IGARD noted the reference in section 5(d) (Benefits) to “*lifestyle choices*”, and noting that not all “*lifestyle choices*” are in fact ‘choices’, asked that this was updated to a different form of words, for example, social or economic determinations of health.

IGARD suggested that section 5(a) be updated to ensure that where appropriate the term “*gender*” was replaced with the term “*sex*” to reflect the available field in the data set requested.

IGARD queried the information in section 5(a) that the applicant is not seeking Cancer Registration data from NHS Digital and asked that further clarity was provided as to why, noting that NHS Digital hold the Cancer Registration data, and would be able to link this for the applicant.

IGARD noted that the applicant had requested data up to 2018, asked that further clarity was provided as to why this was not an ongoing project, since it appeared to be a useful resource.

IGARD advised that they would wish to review this application when it comes up for renewal, given the complexity of the datasets, the sensitivity, and the complex s251 support.

Outcome: recommendation to approve subject to the following conditions:

1. To provide written confirmation that UCL is **not** a joint Data Controller, particularly noting the reference to them being a research partner and being involved in the development and operation of the C&I database.

	<p>2. In respect to the honorary contracts:</p> <ol style="list-style-type: none"> In line with NHS Digital's policy, to provide further detail of what contractual arrangements are in place to protect the data, when accessed by non-substantive employees. For example, counter signatory by the home research institution and / or employer on relevant honorary contracts. To remove the reference to the "<i>DPA 1998</i>" and update as appropriate. To provide written confirmation that MSc and PhD students from UCL, are covered by the honorary contract arrangements and that they also provide the appropriate coverage for a student. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> To update section 5(a), to change the reference from "<i>anonymised</i>" to "<i>pseudonymised</i>", and suggest this change is also made in the Oversight ToR. To update section 5, to amend the references to "<i>mental disorder</i>" to an alternative such as "<i>mental health condition</i>". To update reference to "<i>lifestyle choices</i>" to another form of wording, since they may not be "<i>choices</i>", for example, social or economic determinations of health. To ensure that where appropriate the term "<i>gender</i>" is replaced with the term "<i>sex</i>" to reflect the available field in the data set requested. To clarify why the applicant is not seeking Cancer Registration data from NHS Digital. Noting the applicant is requesting data up to 2018, to clarify why this is not an ongoing project, since it appeared to be a useful resource. <p>The following advice was given:</p> <ol style="list-style-type: none"> IGARD advised that they would wish to review this application when it comes up for renewal, given the complexity of the datasets, the sensitivity, and the complex s251 support. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p>
3.5	<p><u>King's College London: Transition Care in Anorexia Nervosa Through Guidance Online from Peer and Carer Expertise (TRIANGLE) HES Data Application (Presenter: Vicky Byrne-Watts) NIC-272253-P9X9Y-v0.2</u></p> <p>Application: This was a new application for Hospital Episode Statistics (HES) Accident and Emergency (A&E), HES Admitted Patient Care (APC) and Mental Health Services Data Set (MHSDS); for the purpose of a research study, to examine whether the addition of a patient and carer skills-sharing intervention, improves long-term patient wellbeing following hospital inpatient treatment for anorexia nervosa (AN).</p> <p>The study will examine the impact of ECHOMANTRA, a digital intervention that aims to augment inpatient care and reduce relapse by providing support for both patients and carers. The core hypothesis is that ECHOMANTRA might improve the transition from inpatient care to community care for adult AN patients and reduce subsequent bed use and mental health readmissions.</p> <p>The cohort of patients for the study is limited to 370 over 16-year-olds, as that is the number of patients who have consented overall to participate; cohort 1 consists of 198 patients and cohort 2 consists of 172 patients.</p> <p>Discussion: IGARD welcomed the application which came for advice on the consent materials only and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD did not review the application.</p>

	<p>IGARD advised that they were supportive of the research goals outlined and would like to work with NHS Digital and the applicant, to ensure the processing was consistent with the consent provided.</p> <p>NHS Digital advised that there had been ongoing discussion with the applicant, in respect of the request to access mental health admissions data from the MHSDS dataset, for a cohort of approximately 200 patients that had been recruited to an Anorexia Nervosa study; and whether it was reasonable to disseminate mental health data on the basis of the consent materials. IGARD noted the verbal update from NHS Digital in respect of the ongoing discussions with the applicant in respect of the mental health admissions data. IGARD suggested that the applicant may wish to talk to a small number of cohort members, more than 3 but less than 7, with regards to the nature of all the data, including the mental health admissions data, that the cohort members think is flowing, and whether there would be any surprises.</p> <p>In addition, IGARD advised that in any case, and for transparency, the applicant should ensure, that following any discussions, with cohort members, that a more detailed patient information sheet (PIS) or newsletter be disseminated to the entire cohort, that outlined the datasets obtained from NHS Digital.</p> <p>Outcome: IGARD welcomed the application which came for advice on the consent materials only and without prejudice to any additional issues that may arise when the application is fully reviewed.</p>
3.6	<p><u>University of Oxford: How general practice team composition and climate relate to quality, effectiveness and human resource costs: a mixed methods study in England. (Presenters: Vicky Byrne-Watts / Louise Dunn) NIC-344271-Q5X0S-v0.7</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) Accident and Emergency (A&E) and HES Admitted Patient Care (APC) data.</p> <p>The workforce configurations in general practices are highly variable and there is a lack of evidence about what skill mixes and staff deployments generate the best outcomes for patients and savings for health care economies.</p> <p>The purpose is for a study, exploring how team composition and climate affect quality of care, clinical outcomes (effectiveness) and human resource costs in England, in order to inform practice management and commissioning decisions.</p> <p>Discussion: IGARD noted that section 5(a) (Objective for Processing) referred to ambulatory care sensitive conditions (ACSC) “...as the measure of effectiveness, and markers for performance globally as well as in the NHS...”, and queried if the data requested had not been minimised in alignment with those conditions as it was not clear. NHS Digital confirmed that for the HES APC data, the applicant had selected 41 out of the 400 fields available and had therefore minimised the data quite considerably. IGARD noted the verbal update from NHS Digital, and asked that section 3(b) (Additional Data Access Requested) and section 5(b) (Processing Activities) were updated, confirming the data minimisation that was being undertaken, with regards to ACSC, and in line with the NHS Digital DARS Standard for Data Minimisation.</p> <p>In addition, IGARD noted that there were references in section 5 (Purpose / Methods / Outputs) to the “<i>Data Protection Act 1998</i>” (DPA 1998), and asked that as this was now out of date, the references were removed and updated as appropriate to reflect the current legislation.</p>

IGARD queried the conflicting statement in section 5(a) *“This deidentification of records includes production of a hashed NHS number using pseudonymisation algorithm...”*, and asked that either the reference to *“deidentified”* was removed, or that an explanatory note was provided as to what is meant.

IGARD noted the reference in section 5(a) to *“lifestyle choices”*, and noting that not all *“lifestyle choices”* are in fact ‘choices’, asked that this was updated to a different form of words, for example, social or economic determinants of health.

IGARD queried the references within the application to the *“University of Surrey”*, and asked that as they were no longer involved in the study, that the application was updated throughout to remove them.

IGARD noted that ‘Apollo Medical Software Solutions’ had changed its business name to ‘Wellbeing Software Solutions’, and asked that section 5(b) was updated to remove references to *“Apollo Medical Software Solutions”*, after the first reference to explain the change of name, and to use Wellbeing Software Solutions consistently thereafter.

IGARD noted that section 5(b) did not clearly outline the flow of data and the SALT activities taking place, and asked that for transparency, this was updated with a clearer explanation.

IGARD noted that, as previously raised, the Royal College of Practitioners (RCGP) transparency materials did not accurately reflect the processing being undertaken, in particular, the public being told the data was being collected anonymously. This inaccurate description may be deemed to be in breach of the UK General Data Protection Regulation (GDPR). IGARD noted that any transparency materials should be updated and prior to any further applications being considered by IGARD.

In addition, IGARD also asked that a special condition was inserted in section 6 (Special Conditions) that the applicant shall ensure that their public facing transparency materials reflected accurately the processing described in this Data Sharing Agreement (DSA), in particular, such transparency materials should not make any statement or suggestion that the data was collected anonymously.

IGARD noted the excellent patient and public involvement (PPI) work being undertaken, however were concerned about the geographical limitations of the consultation (south east of England), and suggest a more geographically diverse patient group, may better inform the research, given there are many technological means available to convene such groups.

Given the need for revised transparency materials, IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital’s Precedent route, including the SIRO Precedent.

Outcome: recommendation to approve

The following amendments were requested:

1. To update section 3(b) and section 5(b) confirming the data minimisation (as verbally advised in meeting) that is being undertaken, with regards to ACSC, and in line with the NHS Digital DARS Standard for Data Minimisation.
2. In respect of the language in section 5:
 - a) To remove reference to the *“1998 Data Protection Act”*.
 - b) To remove reference to *“deidentified”* in the same sentence as pseudonymised or provide an explanatory note as to what is meant.

	<p>c) To update reference to “<i>lifestyle choices</i>” to another form of wording, since they may not be “<i>choices</i>”, for example, social or economic determinants of health.</p> <ol style="list-style-type: none"> 3. To update the application section 5(b) to remove reference to “<i>Apollo Medical Software Solutions</i>”, after the first reference to explain the change of name, and to use Wellbeing Software Solutions consistently thereafter. 4. To update section 5(b) to make clear the flow of data and the SALT activities taking place. 5. To insert a special condition in section 6 that the applicant shall ensure that their public facing transparency materials reflect accurately the processing described in this DSA, in particular, such transparency materials should not make any statement or suggestion that the data is collected anonymously. 6. To update the application throughout to remove references to the University of Surrey. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD noted the excellent PPI work being undertaken, however were concerned about the geographical limitations of the consultation, and suggest a more geographically diverse patient group, may better inform the research, given there are many technological means available to convene such groups. 2. IGARD noted that, as previously raised, the RCGP transparency materials do not accurately reflect the processing being undertaken, in particular, the public being told the data is being collected anonymously, when it is in fact not. This inaccurate description may be deemed to be in breach of the UK GDPR. IGARD noted that any transparency materials, should be updated and prior to any further applications being considered by IGARD. 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, including the SIRO Precedent.
4	<p><u>Returning Applications</u></p> <p>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.</p> <p>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.</p>

5	<p><u>COVID-19 update</u></p> <p>To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process.</p> <p>The ratified action notes from Tuesday 20th April 2021 can be found attached to these minutes as Appendix C.</p>
6	<p><u>AOB:</u></p> <p>6.1 <u>Information Governance</u></p> <p>A member of NHS Digital's Privacy, Transparency and Ethics – COVID-19 Response Team, attended the meeting to provide a brief update / overview of ongoing work.</p> <p>6.2 <u>IGARD Meeting Quoracy</u></p> <p>In light of the ongoing situation with COVID-19, and following consideration by IGARD members, it has been agreed with NHS Digital that from the 26th March 2020 meeting, the in-meeting quoracy may be temporarily reduced to three members (from four members), which must include a Chair and at least two specialist members. This is to ensure business continuity in the event that COVID-19 impacts on members ability to dial-in to meetings (due to COVID-19 illness or caring for a household member with COVID-19) and to support those IGARD members who have other roles linked to the COVID-19 response. This will be reviewed as and when required, but no less than monthly, and in response to new guidance that is released. This relates to COVID-19 only and the next formal update in IGARD minutes will be at the end of June 2021.</p> <p>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.</p>

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 16/04/21

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-421528-J6S3N-v0.4	The Health Foundation	25/03/2021	<ol style="list-style-type: none"> To update section 1 and section 5 to ensure that that the narrative is consistent with there being a sole Data Controller. In respect of the legal basis: <ol style="list-style-type: none"> To provide written justification from NHS Digital's PTE as to why the pseudonymised data is being disseminated under COPI and include reference to this in the application abstract. To ensure a consistent narrative throughout the application to support the identifiability status of the data. To upload the written justification from NHS Digital's PTE to NHS Digital's CRM system for future reference. 	IGARD members	Quorum of IGARD members	N/A
NIC-421524-R0Y3P-v0.4	Imperial College London	25/03/2021	<ol style="list-style-type: none"> To update section 1 and section 5 to ensure that that the narrative is consistent with there being a sole Data Controller. In respect of the legal basis: <ol style="list-style-type: none"> To provide written justification from NHS Digital's PTE as to why the pseudonymised data is being disseminated under COPI and include 	IGARD members	Quorum of IGARD members	N/A

			<p>reference to this in the application abstract.</p> <p>b) To ensure a consistent narrative throughout the application regarding the identifiability status of the data.</p> <p>c) To upload the written justification from NHS Digital's PTE to NHS Digital's CRM system for future reference.</p>			
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In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 21st April 2021

Application & application version number: DARS-NIC-448252-L2R6Q-v0.2 Organisation name: NHS England Profession Advisory Group Agenda item: 3
<p>PAG advise the applicant that the purpose of use of the GP data is to support vital planning and research for COVID-19 purposes as per the COPI collection.</p> <p>‘PAG were unable to support this application in its current form.’</p>

Attendees	Role	Organisation
Peter Short	Chair, Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Kimberley Watson	Data Approvals Officer	NHS Digital
Pam Soorma	Secretariat	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 20th April 2021

In attendance (IGARD Members): Prof. Nicola Fear (IGARD Specialist Academic Member)
Kirsty Irvine (IGARD Chair / Lay Representative)
Dr. Geoff Schrecker (IGARD Deputy Specialist Chair / IGARD Specialist GP Member)

In attendance (NHS Digital): Karen Myers (IGARD Secretariat)
Kimberley Watson (DARS)
Vicki Williams (IGARD Secretariat)

2	<p>Welcome</p> <p>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 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.</p> <p>The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix.</p> <p>Declaration of interests:</p> <p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19.</p>
2.1 (a)	<p><u>NIC-389914-N9R8R v4.3 Department for Health & Social Care (DHSC) / Imperial College London</u></p> <p>Background: this was an amendment 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.</p> <p>The amendments noted in section 1 (Abstract) were to remove reference to the COPI sunset clause; to extend the date of the Data Sharing Agreement (DSA) to the end of March 2022; to change the storage and processing locations for Amazon Web Services cloud platform; and further request for demographics data for waves 6 and 7.</p>

(b)	<p>A previous version of the application and relevant supporting documents had previously been discussed at the COVID-19 response meetings on the 14th July 2020.</p> <p><u>NIC-393650-B7J6F v3.5 DHSC / Imperial College London / Ipsos Market & Opinion Research International (MORI)</u></p> <p>Background: this was an amendment application from the Department of Health and Imperial College London for record level identifiable demographic data to flow to Ipsos MORI to support the REACT1 study (Real-time Assessment of Community Transmission 1). This application is to support three waves of data being supplied to support stages 4-6 of the antigen testing study, with the surveys being completed in August, September and October 2020. In each wave to achieve the required sample size of 150,000, the names and demographic details of 750,000 individuals aged 5 years and above would be requested. NHS Digital had provided one drop of data in April 2020 under a letter of release from NHS Digital's Information Governance (IG) directorate.</p> <p>The amendments noted in section 1 were to remove reference to the National Health Service (Control of Patient Information Regulations) 2002 (COPI) sunset clause; to extend the date of the Data Sharing Agreement (DSA) to the end of March 2022; to change the storage and processing locations for Data Processor Questback GmbH who changed their service platform to Amazon Web Services; and further request for demographics data for waves 11 to 13.</p> <p>A previous version of the application and relevant supporting documents had previously been discussed at the COVID-19 response meetings on the 4th August and a verbal updated given at the 8th December 2020.</p> <p>IGARD Observations (relate to both applications unless specifically noted):</p> <p><u>NIC-389914-N9R8R v4.3:</u> IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of version 4.3 application and the 21 supporting documents provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD BAU meeting for a recommendation. IGARD members noted that when this application had been presented at the COVID-19 response meeting on the 14th July 2020, they had been provided with version 0.1 of the application summary and 6 supporting documents.</p> <p>IGARD members noted in section 1(a) (Summary) of application NIC-389914-N9R8R v4.3 that against the header "<i>review requested by IGARD</i>" it had been noted as "<i>No</i>". IGARD noted that when they had reviewed the application on the 14th July 2020 they had clearly stated in published action notes "<i>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</i>", and suggested this statement was updated to correctly reference "<i>Yes</i>". If it was not possible to update to "<i>Yes</i>" IGARD requested that the first paragraph clearly articulate that IGARD did request to review the application at a future business as usual (BAU) meeting but that due to operational reasons, the application had progressed via the SIRO precedent.</p> <p>IGARD Members reviewed the previous points raised on the 14th July 2020 in relation to NIC-389914-N9R8R v4.3 and noted that all previous points remained live, until they are deemed to have been satisfied, and drew to NHS Digital's attention the following points raised previously:</p> <ul style="list-style-type: none"> • Noting that NHS Digital had not applied the National Data Opt-outs (NDO) in order to comply with COPI regulations, IGARD Members reiterated their previous comments
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with regard to the application of NDO and that they should be applied which may reduce the numbers of citizens being surprised to be contacted by Ipsos MORI. Contrary to statements in the application suggesting otherwise, IGARD noted that the COPI Regulation did not *require* the NDO to be set aside. Given the number of high profile complaints about the Ipsos MORI survey and the “lower than expected” response rate, IGARD suggested that the NDO should in fact have been applied, as IGARD suggested in July 2020, and taking the approach of other applications for NHS Digital data which also relied on COPI and elected to uphold the NDO.

- Noting that Ipsos MORI’s International Standards Organisation (ISO) recertification audit was due on the 5th August 2020 and that they had confirmed an extension period of 6 months to the 8th March 2021, IGARD members suggested that the special condition in section 6 be deleted and confirmation of such recertification be uploaded to CRM.
- Noting that the application had been updated to reference the “EEA*”, IGARD suggested that NHS Digital check if any data was being held outside of the EEA and to update the application as necessary. In addition, IGARD suggested that NHS Digital review the transparency materials to ensure it is clear that both (a) data is held outside the UK and (b) the categories of recipients holding the data (for example the Ipsos MORI sub-contractors) were clearly articulated.
*European Economic Area
- Noting that section 1 had been updated to state that Ipsos MORI was not considered a Data Controller, that further analysis be undertaken (in line with [NHS Digital's DARS Standard for Data Controllers](#)), however section 1 and section 5(b) (Processing Activities) still retained narrative that was more indicative of Ipsos MORI being a controller; for example, the application stated that Ipsos MORI was making the initial selection. IGARD suggested that further narrative was required to clearly articulate why Ipsos MORI was not a Data Controller.

NIC-393650-B7J6F v3.5: IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of version 3.5 application and the 38 supporting documents provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD BAU meeting for a recommendation. IGARD members noted that when this application had been presented at the COVID-19 response meeting on the 4th August 2020, they had been provided with version 0.2 of the application summary and 17 supporting documents.

IGARD members noted in section 1(a) of application NIC-393650-B7J6F v3.5 that against the header “*review requested by IGARD*” it had been left blank, and suggested this statement was updated to correctly reference “Yes”. If it was not possible to update to “Yes” that the first paragraph clearly articulate that IGARD **did** indicate that they wanted to review the application at a future business as usual (BAU) meeting but that due to operational reasons, the application had progressed via the SIRO precedent.

IGARD members noted that all previous comments in relation to NIC-393650-B7J6F v3.5 when presented on the 4th August and 8th December 2020, remained live until they were deemed to be satisfactorily addressed.

IGARD members noted that the following comments related to both applications either in full or in part, and that both applications should be updated accordingly as per the commentary noted below, in addition to the comments above.

IGARD members noted that reference in section 1 to applications not being presented to IGARD and that these applications, as defined in [IGARD's Terms of Reference](#) (novel, contentious or repercussive) should be prioritised onto IGARD agenda's ahead of other routine applications for data. NHS Digital confirmed that NIC-389914-N9R8R and NIC-393650-B7J6F would be presented to a future IGARD BAU Meeting. IGARD welcomed this approach and suggested that these applications should be prioritised over other applications and that each should be given an extended slot for review.

IGARD members noted the request to remove from section 6 (Special Conditions) the "*COPI* sunset clause*" - notwithstanding the fact that this should be referred to as the "*COPI* Notice*" (since the *National Health Service (Control of Patient Information Regulations) 2002 (COPI) Regulations were not expiring) - queried the justification for the removal of this special condition and asked that relevant Privacy, Transparency and Ethics written confirmation of the rationale for the removal be provided and a copy uploaded to CRM as a future supporting document.

It was not clear to IGARD members the dates of the previous amendments and approvals, and that section 1 should clearly articulate the changes made to the application including dates, for audit and transparency of process.

IGARD members suggested removing reference to "*Article 6(1)(c)*" legal obligation from section 1, since it was not relevant to this application. DHSC and Imperial College London were relying on public task and this article 6 justification was articulated later in the application.

IGARD members queried in section 1 "*a refreshed **anonpop** data drop derived from PDS**" and asked what "*anonpop*" was, since it was a term they had not encountered previously, nor was it a term referenced in NHS Digital's glossary of terms and meanings. IGARD suggested that this be expanded or further explained.

*Personal Demographic Service

IGARD members noted in the application and supporting documents there was reference to demographic data (obtained in a health context) not being confidential patient information, and noted that this was not a universally held view- for example by the medical profession or the National Data Guardian Panel whose view was that demographic data **is** confidential patient information (when gathered in the health care context).

Noting that the Data Controllers have confirmed that they will ensure a UK General Data Protection Regulation (UK GDPR) compliant publicly accessible transparency notice is maintained throughout the life of the DSA, IGARD suggested that the controllers and processor review all complaints raised by members of the public to check if the current transparency materials could be improved.

In addition, IGARD Members noted that throughout the applications it should be clearly articulated with regard to the data destruction mechanism and in what circumstances, if any, Ipsos MORI would need to retain NHS Digital disseminated data.

	<p>IGARD Members noted that section 5 (Purpose / Methods / Outputs) did not reflect the current study objectives and that it should be updated throughout to correctly cover the current activities being undertaken by the applicant.</p> <p>Noting reference in section 5(b) to “<i>all suppliers are GDPR compliant</i>”, IGARD members suggested this statement was updated to more accurately reflect that “<i>all suppliers will comply with the relevant provisions of UK GDPR [and Regulation 7 of COPI]</i>” (the latter only being relevant if the Ipsos MORI sub-contractors were handling CPI, and it was not possible to ascertain that from the application).</p> <p>It was not clear in section 5 which parties were handling what category data and that the section should also be updated to clearly distinguish between the demographic data flowing from NHS Digital and the data subsequently gleaned from the study by the applicant.</p> <p>IGARD members noted that the ethics review documentation provided as a supporting document for NIC-389914-N9R8R v4.3, for example, was from HRA and Health Care & Research Wales (HCRW) and dated 20th April 2020 and that section 5(a) (Objective for Processing) referenced ethical approval from South Central Berkshire B Research Ethics Committee and the Health Research Authority (HRA). However, it was not clear for both applications if the activities undertaken since these reviews had full ethical support, as it appeared that the ethics committee had only appraised the activities up to and including study 4. Since NIC-389914-N9R8R v4.3 included study 5 and the usability and feasibility of the initial study (Study 4) had been concluded, any ethics support should include Study 5 and the substantial increase in participants contacted.</p> <p>IGARD members noted that for potentially repercussive applications that NHS Digital may wish for the assurance of an independent review via a Thursday IGARD BAU meeting and that the discussion today was without prejudice to any additional issues that may arise when the application is fully reviewed.</p> <p>Significant risk areas:</p> <ul style="list-style-type: none"> • Potential digital ethics risk: based on the SD’s provided, HRA ethics support did not appear to be in place for the current activities. • Potential reputational risk: controversy around asserting that demographic data obtained in the context of health care is not classed as confidential patient information. • Potential reputational risk: whether transparency materials for the public clearly articulate who is handling their data (especially Ipsos MORI sub-contractors). • Potential legal risk: whether or not Ipsos MORI should be considered a joint Data Controller. • Potential legal, digital ethics and reputational risk: whether or not Regulation 7 COPI has been satisfied and appropriate documentary evidence provided and catalogued in respect of: IPSOS Mori (COPI Reg 7(2)), storage outside of England and Wales (the COPI Regulation jurisdiction), use of sub-contractors (COPI Reg 7(2) and jurisdiction - depending on whether they are handling CPI). • Potential reputational risk/potentially damaging to public trust: the speed the application was processed resulting in no independent review and recommendation.
2.2	<u>NIC-406871-Q9G2Q v1.6 Department for Health & Social Care (DHSC)</u>

Background: this was an amendment application from the Department of Health to support the NHS Test & Trace work carried out by the DHSC's Joint BioSecurity Centre (JBC). The JBC operates as a specialist data analytical and assessment centre within NHS Test and Trace and the data requested is to support the analysis related to COVID-19 test and trace programme and to support the UK and devolved Government's response to the COVID-19 pandemic including recognising local outbreaks; impact of measures; determining vulnerability within the population; and impact of the virus on different sectors and settings.

The amendments noted in section 1 (Abstract) were to clarify the production details and add in Secondary Use Service (SUS) data; update the agreement in line with the recommended wording from NHS Digital; and add further detail in line with [NHS Digital's DARS Standards](#).

A verbal update had previously presented at the COVID-19 response meetings on the 20th October 2020 and the 26th January 2021.

IGARD Observations

IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of version 1.6 application and the 2 supporting documents provided. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD BAU meeting for a recommendation. IGARD members noted that when this application had been presented at the COVID-19 response meeting on the 20th October 2020 and 26th January 2021 it had been a verbal update only and they had not been provided with any documentation.

IGARD members noted in section 1(a) (Summary) of application that against the header "review requested by IGARD" it had been noted as "No". IGARD noted that when they had received the verbal update in January 2021, they had clearly stated in published action notes: *"As noted previously, IGARD members would welcome sight of both the application and relevant supporting documentation and would expect that a future amendment or renewal would go through the usual DARS – IGARD process to allow for a full independent review."*, however section 1 (Abstract) noted that *"this application will be going under the SIRO precedent due to the urgent nature and high profile of the request, the backlog of the IGARD BAU agenda, the fact that v0 has expired and data needs to go out quickly and urgently to support the programme (it was not delivered under v0)"*, and suggested this statement was updated to correctly reference "Yes". If it was not possible to update to "Yes" that the first paragraph clearly articulate that IGARD did request to review the application at a future BAU meeting but that due to operational reasons, the application had progressed via the SIRO precedent.

IGARD members also noted that reference in section 1 to applications not being presented to IGARD due to a "backlog" or because they were "high profile" was not correct, and that it this application, as defined in [IGARD's Terms of Reference](#) (novel, contentious or repercussive) should have been prioritised onto IGARD agendas ahead of other routine applications for data.

It was also not clear to IGARD members within section 1 the dates of the amendments and approvals and that section 1 should clearly articulate the changes made to the application including dates, for audit and transparency of process.

IGARD members noted in in section 3(b) (Data Requested) that for the SUS Payment by Results Spells that the legal bases cited were Article 9(2)(i), 9(2)(g) and 9(2)(j) and queried that rationale for three Article 9's.

	<p>Noting NHS Digital's DARS Standard for Data Minimisation, IGARD were unclear what data minimisation had been undertaken on the data which has flowed to the applicant and that this should be clearly articulated throughout the application, noting the large volume of data being disseminated in order to comply with UK GDPR, as embodied in NHS Digital's DARS Standard for Data Minimisation.</p> <p>IGARD members reiterated their previous comments that section 5 (Purpose / Methods / Outputs) should clearly articulate how the work being undertaken differed from other work in this area to address the public health response (to assuage any concerns about duplication of effort between various health bodies and/or excessive handling of data).</p> <p>IGARD members noted that the section 5 of the application formed NHS Digital's data release register and noting the three outputs outlined in section 5(c) (Specific Outputs Expected, including target dates) appeared to be internal outputs, queried the external outputs generated with the NHS Digital data such as providing local level reports weekly, and as outlined in NHS Digital's DARS Standard for Expected Outcomes. In addition, and noting NHS Digital's DARS Standard for Expected Measurable Benefits, suggested that section 5(d) (Benefits) be updated to articulate the benefits accrued to the health and care system. Noting that the applicant had had the data since October 2020, further Yielded Benefits should be included in section 5(d)(iii) (Yielded Benefits) linking back to the outputs and benefits, such as informing at a local level. A quick review in meeting showed several outputs and benefits in the public domain on the .gov website which could have been carried over into the application to populate NHS Digital's data release register.</p> <p>Significant risk area:</p> <ul style="list-style-type: none"> • Potential reputational risk/potentially damaging to public trust: the speed the application was processed resulting in no full independent review of the application or supporting documentation. • Potential digital ethics and legal risk: data minimisation not complying with UK General Data Protection Regulation (UK GDPR) and potential perception of the duplication of effort with other national bodies. <p>Action: IGARD would welcome hearing directly from the JBC as to how their work using NHS Digital data differs from other national bodies and would welcome the opportunity to discuss their work further and plans for the future.</p>
3	<p><u>AOB</u></p> <p>There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.</p>