

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 28th May 2020

In attendance (IGARD Members): Paul Affleck, Maria Clark (Alternate Deputy Chair), Prof. Nicola Fear, Kirsty Irvine (Chair) (Items 2.5 and Item 4), Dr. Imran Khan.

In attendance (NHS Digital): Louise Dunn, Karen Myers, Bethan Thomas, Kimberley Watson, Vicki Williams.

In attendance (NHS Digital) Observer: Zuzana Hancock (ZH) (Observer: 2.1-2.4)

Not in attendance (IGARD Members): Dr. Geoffrey Schrecker, Dr. Maurice Smith.

1	<p>Declaration of interests:</p> <p>Prof. Nicola Fear noted she was a member of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 21st May 2020 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	<p>Data Applications</p>
2.1	<p><u>St George's, University of London: MR1485 - Development of a linked, de-identified database resource for research into the health, mortality and educational outcomes of children with a congenital anomaly (Presenter: Louise Dunn) NIC-64474-V4B2D</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data, Civil Registration data, and identifiable Demographics data. The British and Irish Network of Congenital Anomaly Researchers (BINOCAR) is a collaboration of congenital anomaly registries which had been involved in the surveillance of congenital anomalies from as early as 1985 until 2015. Congenital anomalies are developmental disorders of the embryo and foetus. Between 3-5% of babies born have a congenital anomaly; this equates to about 28,000 babies affected each year in England and Wales. The purpose is to enable future, approved outcomes-research into the long-term survival, health and educational achievement of children with congenital anomalies.</p> <p>NHS Digital advised IGARD that the table in 3(b) (Additional Data Access Requested) stated that HES Admitted Patient Care data was required from 1989 onwards, however advised that this was an error, and that the table and application would be amended to reflect the correct year of 1997 onwards.</p> <p>NHS Digital also noted reference to 'we' within section 5 and that this had been amended.</p> <p>Discussion: IGARD noted the update from NHS Digital in relation to the HES Admitted Patient Care data years requested and supported the amendment to the application to reflect the correct information and the removal of 'we'.</p> <p>IGARD queried the reference in section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) <i>"The public benefit of this work will be helping parents make more fully informed decisions"</i> and asked that this was updated to be specifically clear of what was meant by the statement, and that if this was relating to the possible termination of a pregnancy to make this explicitly clear and transparent.</p>

In addition, IGARD also noted the references throughout the application to decisions being made on the *“future of affected pregnancies”, and the reference in section 5(c) (Specific Outputs Expected) that the research was “to support the prevention of congenital anomalies”* and asked that both of these statements were amended and / or updated to be explicitly clear on what was meant by this.

IGARD queried the applicant’s request for identifiable Demographics extract as this was not clear within the application, and asked that section 5(b) (Processing Activities) was updated with a clear justification of why this dataset was required.

IGARD noted that supporting document 8, the EU funding questions, stated that data flowing to Ulster University for the wider EU project would be in aggregated form with small numbers suppressed, however this was not reflected in the application, and asked that section 5(b) was updated to reflect this.

IGARD queried a discrepancy between the application and supporting document 1.0, the protocol, in relation to the end point of the research, and asked that confirmation was provided of whether this was earliest of either when the child reaches the age of 10 or the year 2015, and that the application was amended accordingly. In addition, IGARD asked that further justification was provided in section 5, as to why the data had been requested for the period of time set out in the application, noting that data was requested post 2015.

IGARD noted that NHS Digital had reviewed the applicant’s Privacy Notice and that this had met NHS Digital’s Standard for privacy notices and had been published, however IGARD queried information within the Privacy Notice, for example, the potentially misleading wording around the patients’ right to withdraw, and suggested that the applicant reviewed this.

IGARD queried information in section 5(b) (Processing Activities) in relation to who would be accessing the data, and asked that this was amended to confirm that only substantive employees of the Data Processors and Data Controller would have access to the data, and that any change to this, would be subject to an amendment application submitted to NHS Digital.

In addition, IGARD also queried who would have access to the subsets of linked data, due to a mismatch of the organisations listed in the application and the Protocol, and asked that section 1 and section 5(a) (Objective for Processing) were updated with confirmation of the actual organisations accessing the linked data.

IGARD noted that the application referred to *“University Hospitals Bristol NHS Foundation Trust”* and advised NHS Digital that they had now merged with Weston NHS Foundation Trust, and asked that the application was updated to correctly reflect the Trust’s new name *“University Hospitals Bristol and Weston NHS Foundation Trust”*.

IGARD queried the reference in supporting document 4, 2018 correspondence from the Department of Health (now Department of Health and Social Care), that referred to funding for the project, and asked that section 1 was updated clarifying the funding, what it related to and how it related to this application.

IGARD queried information within supporting document 6.1, Guidance and Procedures for obtaining British and Irish Network of Congenital Anomaly Researchers (BINOCARD) data, that stated identifiable data may be shared with the *“appropriate CAG and Ethics approval”*, and asked that section 5 was updated to clarify that NHS Digital had not given their approval for the sharing of any identifiable data in any circumstance.

IGARD noted that the Health Research Authority’s Confidentiality Advisory Group (HRA CAG) approval expires in June 2021 and asked that a special condition was inserted in section 6

(Special Conditions) stating that the applicant must destroy the identifiers, or to seek further HRA CAG approval before this date.

IGARD suggested that the applicant may wish to consider any future plans for the research and data and whether the cohort should be flagged for further research (subject to the usual consents) and if so, to update the application accordingly.

IGARD suggested that on renewal the applicant should have clear evidence of the Patient and Public Involvement (PPI) that has taken place, including but not limited to lived experience, not just the clinical data.

In addition, IGARD also 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 Summary: recommendation to approve subject to the following conditions:

1. To be explicitly clear in section 1 and section 5 of what is meant by the statement "*The public benefit of this work will be helping parents make more fully informed decisions*", and if this is relating to the termination of a pregnancy to make this explicitly clear and transparent.
2. To provide justification in section 5(b) of why the identifiable Demographics extract dataset is required.
3. To provide written confirmation in section 5(b) that data flowing to Ulster University for the wider EU project would be in aggregated form with small numbers suppressed.
4. To confirm that the end point of the research is the earliest of either:
 - a) when the child reaches the age of 10 or the year 2015 given the discrepancy between the application and the protocol, and amend the application accordingly;
 - b) provide justification in section 5 therefore as to why the data has been requested for the period of time set out in the application noting that data is requested post 2015.
5. The applicant to review the published Privacy Notice including (but not limited to) the potentially misleading wording around the patients' right to withdraw.

The following amendments were requested:

1. To amend the application throughout to be explicitly clear on what is meant by decisions being made on the "*future of affected pregnancies*".
2. To update section 5(c) to clarify what is meant by the statement that the research is "*to support the prevention of congenital anomalies*".
3. To amend section 5(b) to confirm that only substantive employees of the Data Processors and Data Controller will have access to the data, and that any change to this, would be subject to an amendment application submitted to NHS Digital.
4. To update the application throughout to ensure that any reference to "University Hospitals Bristol NHS Foundation Trust" is amended to "*University Hospitals Bristol and Weston NHS Foundation Trust*".
5. To provide clarity in section 1 on the reference in SD4 to the DHSC funding, what this relates to and how this relates to this application.
6. To provide confirmation in section 1 and section 5(a) of who will have access to the subsets of linked data, due to a mismatch of the organisations listed in the application and Protocol.
7. To clarify within in section 5 that in light of the information provided in SD 6.1, NHS Digital have not given their approval for the sharing of any identifiable data in any circumstance.

	<p>8. To insert a special condition in section 6 that the applicant must destroy the identifiers or seek further HRA CAG approval before June 2021.</p> <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. To consider any future plans for the research and data and whether the cohort should be flagged for further research (subject to the usual consents) and if so, to update the application accordingly. 2. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 3. IGARD suggested on renewal that the applicant should have clear evidence of the PPI that has taken place, including (but not limited to) lived experience, not just the clinical data. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. <p>It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.</p>
2.2	<p><u>Group application x 3 CCGs¹: 3 CCGs within Coventry and Warwickshire STP - Comm, including GP data (Presenter: Kimberley Watson) NIC-238282-X0B6H</u></p> <p>Application: This was a renewal application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data Sets (CRD), Patient Reported Outcome Measures Data Set (PROMs) and National Diabetes Audit Data Set (NDA); and an amendment to 1) add South Warwickshire GP (SWGPs) and South Warwickshire NHS Foundation Trust (SWFT) as Data Processors, 2) to add Microsoft Azure as a processing and storage location, and 3) to add the Cancer Waiting Times (CWT) standard template wording within the processing activities.</p> <p>The purpose of the application is to provide intelligence to support the commissioning of health services.</p> <p>Discussion: IGARD noted the request to add the two new Data Processors, and queried what the benefits were of this addition, given the number of other Data Processors listed within the application. IGARD asked that a clear justification was provided in section 5 (Purpose / Methods / Outputs) for the addition of the two new Data Processors to the Data Sharing Agreement (DSA) and clarification of the benefits this would bring.</p> <p>IGARD noted that the GP Practice where the patient was registered would be able to re-identify patients, only when they needed to do so for direct care purposes, and asked that in respect of the pseudonymised data conversion process, section 5(a) (Objective for Processing) was updated with a clear outline of the process and how easily this could be reversed and confirmation of how data opt outs would apply. In addition, IGARD also asked that supporting document 2, the data flow diagram was updated to include all relevant data flows.</p>

¹ NIC-238282-X0B6H NHS Coventry and Rugby CCG, NHS South Warwickshire CCG and NHS Warwickshire North CCG

	<p>A number of acronyms were noted throughout the application, and IGARD asked that these be updated to ensure that all acronyms upon first use, were correct and clearly defined and that it also had a further supportive explanation in language suitable for a lay reader.</p> <p>IGARD queried the volume of processing and storage locations within the application and asked that section 1 (Abstract) and section 5 were updated to provide an explanation of this; and to clarify if consideration had been given to consolidating these in light of the increased risk.</p> <p>IGARD noted and endorsed NHS Digital's review that the applicant did not meet NHS Digital's Standard for privacy notices.</p> <p>Outcome Summary: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. To provide a clear justification in section 5 for the addition of the two new Data Processors to the DSA and clarification of the benefits they will bring. 2. In respect of the pseudonymised data conversion process, in section 5(a): <ol style="list-style-type: none"> a) to provide a clear outline of the process and how easily this can be reversed; b) to confirm how data opt outs apply; c) to update the data flow diagram to include all relevant data flows. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To amend the application throughout to ensure that all acronyms upon first use within the document are correct and within the published sections be defined and further explained, as may be necessary for a lay reader. 2. To provide an explanation in section 1 and section 5 of the volume of processing and storage locations; and to clarify if consideration has been given to consolidating these in light of the increased risk. <p>It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.</p>
2.3	<p><u>London School of Economics (LSE): Investigating the impact of the Health in Pregnancy Grant on birth outcomes in England, 2009-2011 (Presenter: Kimberley Watson) NIC-309029-P7H1D</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data, for the purpose of a stand-alone research project, building on previous work conducted by the London School of Economics (LSE) evaluating the Health in Pregnancy Grant (2009-2011). This grant was a lump sum of £190.00 given to all pregnant women in the UK from the third trimester of pregnancy, regardless of income or work status. The aims of the grant were to reduce low birthweight; and to reduce prematurity. Both low birthweight and prematurity are associated with low-income and lack of funds during pregnancy for healthy nutrition and lifestyle. The rationale of the grant, therefore, was that boosting women's incomes during pregnancy, would facilitate the purchase and consumption of healthier food, invest in healthy lifestyle choices and reduce any financial stress caused by having a baby</p> <p>Discussion: IGARD noted that NHS Digital had reviewed the applicant's Privacy Notice and that this had met NHS Digital's Standard for privacy notices, however IGARD queried point 11, in relation to the rights available to individuals in respect of the processing, in particular the reference to National Data Opt Outs having been applied, noting that the data requested was pseudonymised. IGARD therefore asked that written confirmation was provided that the applicant had reviewed the published Privacy Notice including, but not limited to, ensuring there were no misleading statements and that it was clear that data opt out would not apply as the data was pseudonymised data.</p>

IGARD noted that the period of the grant was from 2009 – 2011, and therefore asked why the applicant was requesting data from 2006 – 2014/15; NHS Digital advised that this was due to the study comparing data for a period of 3 years before the Grant was introduced and for three years after. IGARD noted the explanation from NHS Digital and asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) were updated with a clear justification of the years of data requested.

IGARD queried if there was a time restriction on the funding, noting that the work was due to be completed in July 2020, and asked that section 5 and section 8 (Period and Funding) were updated to make this explicitly clear.

In addition, IGARD asked that section 5 was updated to confirm that the funder would not place any restrictions or limitations on any publications.

IGARD queried the information provided in section 5(c) (Specific Outputs Expected) when describing the outputs and timeframes, and asked that the language was revised to ensure these were realistic and achievable.

IGARD also noted the language used within the application and asked that this was revised and written in a language suitable for work in the maternity sphere, in particular removing the references to “*delivery*” and replacing it with the word “*birth*”.

IGARD queried the reference in supporting document 1, the data flow diagram, to there being “*two Data controllers*” and asked that confirmation was provided that there was only one Data controller as listed in the application.

IGARD noted that the “*take-up rate*” data of the grant was not recorded and suggested that the applicant may wish to consider how the absence of this data would affect the research outcomes.

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 Summary: recommendation to approve subject to the following condition:

1. NHS Digital to provide written confirmation that the applicant has reviewed the published Privacy Notice including (but not limited to) ensuring there are no misleading statements and ensuring that it is clear that data opt out will not apply as the data is pseudonymised data.

The following amendments were requested:

1. To update section 1 and section 5 to provide a clear justification of the years of data requested.
2. To update section 5 and section 8 to make explicitly clear that there is not a time restriction on the funding given the work is due to be completed in July 2020.
3. To confirm within section 5 that the funder will not place restrictions or limitations on any publications.
4. To revise the language in section 5(c) when describing the potential outputs and timeframes to ensure that these are realistic and achievable.
5. To revise the language throughout the application to ensure this is written in language suitable for work in the maternity sphere and in particular remove reference to ‘*delivery*’ and replace it with the word ‘*birth*’.
6. To confirm that there is one only Data Controller as listed in the application.

The following advice was given:

1. IGARD suggested that the applicant may wish to consider how the absence of the “*take-up rate*” data will affect the research outcomes.

	<ol style="list-style-type: none"> 2. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. <p>It was agreed the conditions would be approved Out of Committee (OOC) by the IGARD Alternate Deputy Chair.</p>
2.4	<p><u>Imperial College London: Imperial College London research into UK Health Policy Reform (Presenter: Kimberley Watson) NIC-366210-V2H5M</u></p> <p>Application: This was a renewal application for pseudonymised Hospital Episode Statistics (HES) and Patient Reported Outcome Measures (PROMs) data; and an amendment to 1) request Civil Registrations data, 2) request HES Critical Care data from 2008/09 to 2020/2, and 3) to change storage addresses. From 2000 onwards, there have been reforms to the NHS in England which have been some of the most radical in the Organisations for Economic Cooperation and Development (OECD). These reforms consisted of a series of policy initiatives, beginning in the early part of the 2000s and carried out for the next 10 years, which were intended to improve care for patients. The purpose therefore, is to support ongoing research into the impact for patients and health service users of UK health policy reforms begun in the 2000s; and to examine the impacts of Covid-19 and weather-related shocks on patient care.</p> <p>Discussion: IGARD noted the following their last review of this application on the 6th December 2018, IGARD had advised that when the application returned for renewal, they would expect to see further information and evidence with regard to expected benefits and yielded benefits for the public and patients. IGARD queried the information provided in section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) of the application in relation to the outputs and benefits, and asked that in light of the amount of data requested that confirmation was provided of who the key stakeholders were, and how they would allow for the aspirations of the study to be met, and that details were included of any links, connections, channels and avenues available through these stakeholders.</p> <p>In addition, IGARD also asked for evidence of the specific historical benefits and yielded benefits in relation to healthcare, noting that this information was absent from the application.</p> <p>IGARD also queried how the additional COVID-19 purpose would provide a wider public benefit, and asked that confirmation of this was provided, or justification of why this information was not currently available.</p> <p>IGARD noted and endorsed NHS Digital's review that the applicant did not meet NHS Digital's Standard for privacy notices, in addition IGARD also noted that the applicant's Privacy Notice was aimed at research collaborators and not the research subjects; and asked that NHS Digital provide written confirmation that the applicant had provided a General Data Protection Regulation (GDPR) compliant Privacy Notice, including, but not limited to, ensuring it was study specific and reflected the volume of data held / requested.</p> <p>IGARD noted that section 8 (Period and Funding) was incomplete and asked that this section was completed with clarification of the source of the funding for this application.</p> <p>IGARD noted that in 2019, all Imperial College data servers were relocated to a new location in Slough, and queried if an amendment application had been submitted via NHS Digital and that written confirmation was provided confirming this.</p>

	<p>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.</p> <p>Outcome Summary: recommendation to approve subject to the following conditions:</p> <ol style="list-style-type: none"> 1. In respect of the outputs and benefits (section 5c and 5d), and in light of the large amount of data requested, to provide: <ol style="list-style-type: none"> a) confirmation of who the key stakeholders are and how they will allow for the aspirations of this study to be met and to include details of any links, connections, channels and avenues available through these stakeholders; b) evidence of the specific historical benefits and yielded benefits in relation to healthcare; c) confirmation of how the additional COVID-19 purpose will provide a wider public benefit, or to provide justification of why this information is not currently available. 2. NHS Digital to provide written confirmation that the applicant has provided a GDPR compliant Privacy Notice, including (but not limited to) ensuring it is study specific and reflects the volume of data held / requested. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 8 to provide clarification of the source of funding for this application. 2. To provide written confirmation that the amendment to the storage location in 2019 was via an amended DSA. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that they would wish to review this application again 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. <p>It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.</p>
<p>2.5</p>	<p><u>Informal Engagement on GPES Data for Pandemic Planning and Research (COVID-19) Templates – Briefing Paper (Presenter: Bethan Thomas)</u></p> <p>An initial briefing on General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (COVID-19) (abbreviated to GDPPR) was given to IGARD on April 21st. At this briefing it was referred to as GP Data for Planning and Research (GPDPR).</p> <p>The GDPPR Data Provision notice was published on 14 May 2020, along with the application process that is specific to this dataset and specifies that all applications will be submitted for approval to IGARD, once the Royal College of General Practitioners (RCGP) and British Medical Association (BMA) assurance review has taken place.</p> <p>The briefing paper was to inform IGARD about templated content that are being developed by NHS Digital for Clinical Commissioning Groups (CCGs), Local Authorities (LAs) and Integrated Care Systems (ICs) applications to lessen the workload on the system. These applications will still go through the agreed process of the (RCGP) and the (BMA) assurance review and IGARD review.</p> <p>Discussion: IGARD welcomed the briefing paper and thanked NHS Digital for providing it. IGARD made the following initial comments and advised that further comments would be shared with NHS Digital out of committee in due course.</p>

	<p>IGARD looked forward to receiving an updated briefing note at a future IGARD meeting along with the updated templated applications for CCGs, LAs and ICSs:</p> <ol style="list-style-type: none"> 1. To advise on how data destruction will be monitored or transition arrangements will be implemented for recipients at the expiry of the COPI notice, and particularly, how recipients may transition to the yet-to-be onboarded GP Data for Planning and Research dataset. 2. To confirm that the National Data Guardian's Office have been briefed on these final agreed arrangements for GPES Data for Pandemic Planning and Research. 3. To amend the application throughout 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. 4. To ensure the consistent use of either "COVID-19" or "Coronavirus" throughout the templates. 5. To amend section 4 of the template(s) to state the Privacy Notice is either "compliant with GDPR" or "compliant with the ICO guidance". 6. To ensure that all repetitive text within the template(s) is removed if not relevant. 7. To ensure the relevant COPI Regulation is cited under the legal basis for the recipient processing the data and to consider making an express statement addressing how Local Authorities come under Reg 3(3)(b) "persons employed or engaged for the purposes of the health service".
3	<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> <ul style="list-style-type: none"> • NIC-82493-P8Y3N University of Essex • NIC-88623-F2H1Q Royal College of Anaesthetists • NIC-26815-F8H6B Royal College of Surgeons <p>IGARD welcomed the three applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report.</p> <p>Moving forward, IGARD agreed that COVID-19 and Control of Patient Information (COPI) regulation 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.</p>
4	<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 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.</p> <p>The ratified action notes from Tuesday 26th May 2020 can be found attached to these minutes as Appendix B.</p> <p>IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.</p>

5	<p><u>AOB:</u></p> <p>There was no further business raised, the IGARD Alternate Deputy Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>
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Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 22/05/20

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-148232-CPHLL	National CJD Surveillance Unit	23/04/20	1. To provide further background information or clarification of the consideration taken into account when seeking s251 support and the conclusion that the activity is for surveillance; and clarification if, for example Regulation 3, Health Service (Control of Patient Information) Regulations 2002 was considered as an alternative route.	IGARD members	Quorum of IGARD Members	N/A
NIC-233512-B7C4W	Northgate Public Services (UK) Limited	30/04/20	1. To provide further details of the role and responsibility of the auditing neurosurgeon and justification of how they will be using the duplicate set of NHS Digital data held on the laptop in carrying out that role on remote sites.	IGARD Members	Quorum of IGARD Members	<p>IGARD asked that a final sentence was also included stating “Accordingly, it is necessary for the SBNS audit lead to have the NHS data with them on a laptop on site.”</p> <p><i>IGARD members also noted that section 5(b) still refers to a specific laptop product – the MacBook Pro and asked that section 5(b) of the application was updated to remove reference to the MacBook Pro and suggested the following sentence “the SBNS surgeon’s laptop will be appropriately</i></p>

						<i>specified for the task with security features including“</i>
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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 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, 26 May 2020

In attendance (IGARD Members): Prof. Nicola Fear, Kirsty Irvine (Chair), Dr. Geoffrey Schrecker.

In attendance (NHS Digital): Vicky Byrnes-Watts, Garry Coleman (part), Catherine Day, Louise Dunn, Liz Gaffney (part), Frances Hancox, Karen Myers (Observing), Kimberley Watson, Vicki Williams.

1	<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 any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual DARS process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix.</p> <p>Declaration of interests:</p> <p>Nicola Fear noted a professional link with University College London [NIC-372269-N8D7Z] and that she knew members of the study team, however she had no specific connection with the application and it was agreed that this was not a conflict of interest.</p> <p>Nicola Fear noted she was a member of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.</p>
2.1	<p><u>NIC-372269-N8D7Z University College London (UCL)</u></p> <p>Background: This was a new application with regard to understanding community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour. Although the levels of COVID-19 are beginning to decrease it is likely that COVID-19 may start to spread again when the Government lift current restrictions and Public Health authorities are considering a wide range of approaches to limit the spread of infection as we come out of lockdown. The 'Virus Watch' study aims to evaluate a number of approaches and which are likely to help inform NHS planning and the national public health response.</p> <p>IGARD Observations:</p> <p>IGARD members were unclear as to whether this was a "flagged" cohort, which would only necessitate a single flow of identifiable data, or whether this was not the case, necessitating a flow of identifiable data for each data collection of pseudonymised data from NHS Digital. Accordingly, IGARD members suggested that, if identifiable data is required to flow to NHS Digital for each collection of pseudonymised data, NHS Digital discuss with the applicant their plan to re-consent children who reach 16 years of age, since recruitment was ongoing until 2021 and follow up for a further five years.</p>

	<p>IGARD members noted that supporting document 6, <i>NHS Digital data linkage request summary</i>, noted an additional aim of the study was to look at how social distancing has a wider impact on other aspects of the cohort's life (including hospital attendance). IGARD members noted that this secondary aim was not reflected throughout the suite of documentation provided and suggested that it be evidenced that it had appropriate approvals via the Ethics committee and that it was integrated into the design of the study to ensure the cohort were aware of this secondary aim.</p> <p>IGARD members noted the applicant was applying for virology data from Public Health England which they were content with, noting it was also mentioned within the consent materials provided, however it was not clear within the documentation what NHS Digital data was being disseminated and suggested that this be made explicitly clear. In addition, IGARD members suggest that the applicant may wish to consider PHE's Second Generation Surveillance System (SGSS) data specifically for the COVID-19 test result data and PHE's COVID-19 Hospitalisation in England Surveillance System (CHESS), both datasets held by NHS Digital.</p> <p>It was noted that a substantial amount of data was being requested a cohort of approximately 25,000 households and that the applicant may wish to consider appropriate rationale for the quantum of data requested, and in line with NHS Digital's relevant data minimisation standard. In addition, IGARD members noted seemingly dated wording in reference to the 'lead householder' and suggested that applicant may wish to update the terminology to 'designated household contact' or similar.</p> <p>IGARD members raised a query with regard to those households which are 'split', where a child lives part of the week with each parent or another caregiver, and suggested that the applicant may wish to consider if both households would need to consent to be part of the study or other such considerations.</p> <p>IGARD members noted that supporting document 1.2, Adult PIS Final 21.05.20, used restrictive language "...Access to personal data that could be used to identify you will be strictly limited to a small number of trained researchers at UCL..." and that when read in conjunction with the consent materials was acceptable, however IGARD members noted that the applicant must be sure that use of such language would not constrain their future activities.</p>
2.2	<p><u>NIC-204903-P1J7Q Imperial College London</u></p> <p>Background: This is an amendment application for the Small Area Health Statistics Unit (SAHSU) to increase the data dissemination frequency from annual to monthly to enable SAHSU to undertake COVID-19 related research studies. In addition NHS Digital noted that the application had been updated to add ECDS data as HES Accident & Emergency data is no longer being produced, and adding a new data storage location (Virtus) and removing a previous storage location (St Mary's campus) due to a planned server move.</p> <p>NHS Digital noted that section 3a noted that applicant was currently holding monthly data, however this was a system error and the applicant was currently holding only annual data.</p> <p>IGARD Observations:</p> <p>IGARD members noted the increase in frequency from annual to monthly disseminations of data, but noted that there was little additional detail in section 5 of the application and</p>

	<p>suggested the applicant be clear about the additional outputs and benefit to support the COVID-19 work.</p> <p>IGARD members noted and endorsed Health Research Authority Confidentiality Advisory Group (HRA CAG)'s view that the applicant's privacy notice was long and at times used technical language, and that a shorter lay version that linked to a full version should be considered, thereby using a layered approach to transparency as advocated by the Information Commissioner's Office (ICO). IGARD members suggested that NHS Digital may wish to consider a special condition to ensure the applicant addresses the issues raised, before further data is disseminated.</p> <p>IGARD members noted the query raised by CAG in respect of a project-specific opt out and asked for the applicant to expressly note if that was being incorporated or if they were relying on the national data opt out.</p> <p>IGARD members noted reference within section 3 of the application to 'ordnance survey (OS) grid reference'. NHS Digital noted that the Hospital Episode Statistics (HES) dictionary of terms stated that the grid reference was 4 digits eastings, 5 digits northings, however IGARD members noted this area was considerably smaller than postcode area and suggested that any disseminated of OS grid reference be no more identifying than a postcode, or provide additional detail that the applicant acknowledges the small size of the field but how the process it means it is not identifying to the level of 10m by 1m.</p> <p>ACTION: separate to this application NHS Digital should speak to the HES dictionary author to discuss the grid referencing terminology and ensure it accurately reflects current disseminations and that the OS grid reference was correctly designated as "non identifying" data.</p>
2.3	<p><u>5 x Oxford Studies</u></p> <p>Background: NHS Digital provided a brief update with regard to five applications from the University of Oxford: three of which were observational and two of which were clinical trials. NHS Digital noted they were all at an early stage and discussions with the applicant were ongoing.</p> <p>IGARD Observations:</p> <p>IGARD members noted the verbal update and suggested that NHS Digital work with the applicant with regard to the appropriate legal bases for each of the applications presented.</p> <p>IGARD queried if this would be one application with one dissemination of data for a number of projects, or if it would be one dissemination of data with a number of applications for the observational studies. NHS Digital noted that technically it may be easier to have one dissemination of data and one application, however this would be based on the purpose, how the studies interlinked and consideration of the protocols.</p> <p>IGARD members welcomed the verbal update and looked forward to receiving the applications in due course.</p>
2.4	<p><u>NIC-381078-Y9C5K Cardiovascular Disease Trusted Research Environment (CVD TRE) for COVID-19</u></p> <p>Background: The applicant would like to provide CVD TRE for England to perform analysis of linked, nationally collated healthcare datasets to enable the timely research on the effects /</p>

	<p>impacts of CVD on COVID-19 and the indirect impact of COVID-19 on CVD; the sharing of noted research across the four nations of the UK; future proofing an enduring CVD TRE post COVID-19.</p> <p>IGARD Observations:</p> <p>IGARD members were unclear if there was one overarching NHS Digital TRE with a number of sub-sites for each particular condition such as CVD, or cancer and suggested that a further discussion item be included on next week's agenda.</p> <p>IGARD members noted that it was a sensible approach and good to understand the practicalities of this TRE and the next steps, but needed more information about how it fitted together, who was accessing the data and how researchers would use the data in relation to COVID-19 and the overarching NHS Digital TRE.</p> <p>NHS Digital noted that they had a number of queries for NHS Digital's information governance department and the datasets for this TRE and IGARD supported establishing a clear legal basis for the collection, holding and dissemination of TRE data (noting that there may be a different legal basis depending on which data sets were flowing and who the applicant was).</p> <p>IGARD noted that GP data in relation to COVID-19 would only be available through the TRE, however with the necessary safeguards around GP data including relevant approvals, queried if the TRE was the most appropriate place to keep GP data, since it would not be appropriate to give a 'blanket approval' for GP data and may therefore obviate some of the potential benefits from a TRE arrangement.</p>
2.5	<p><u>NHS England / NHS Improvement</u></p> <p>Background: NHS Digital noted that NHS England and NHS Improvement's overarching Data Sharing Agreement (DSA) would be updated to allow the ability to share aggregated data small numbers unsuppressed to a number of key organisations including CCG's and Charities. NHS Digital had requested a copy of NHS England's terms of use document in order to review and then amend the DSA to allow for the onward sharing of aggregated data with small numbers unsuppressed.</p> <p>IGARD Observations:</p> <p>IGARD members noted that they had recently reviewed the NHS England and NHS Improvement application at a Thursday BAU meeting of IGARD and that it had been approved for 3 months.</p> <p>IGARD members noted that the application would be coming to a full BAU meeting of IGARD and suggested that along with an updated application summary, that a copy of the terms of use were provided along with a clear rationale as to why unsuppressed data was required.</p> <p>In addition, IGARD members noted that the applicant may wish to consider the risk of accidental disclosure of confidential information when using data with small numbers unsuppressed, particularly in the context of a CCG employee working in the same geographical area as a family member or associate and that a statement be included that the risk has been considered and accepted or mitigated as far as possible.</p>
2.6	<p><u>NIC-15625-T8K6L Clinical Practice Research Datalink (CPRD)</u></p>

	<p>Background: This was an update to the application presented for advice on the 12th May and the verbal update to the COVID-19 Response meeting on the 19th May 2020.</p> <p>The application was an amendment to extend the current Data Sharing Agreement (DSA) to include linkage with PHE's Second Generation Surveillance System (SGSS) data specifically for the COVID-19 test result data and linkage with PHE's COVID-19 Hospitalisation in England Surveillance System (CHESS), both datasets held by NHS Digital. The linkage is permitted by PHE and should be conducted under the recent COVID-19 notices under Reg 3(4) of the Health Service Control of Patient Information (COPI) Regulations 2002.</p> <p>NHS Digital noted that the application had been updated in line with the verbal update given last week.</p> <p>IGARD Observations:</p> <p>IGARD members noted the special condition in section 6 of the application that <i>"SGSS and CHESS data (in line with PHE cancer registration data) cannot be included in research projects outside of the EEA (unless The European Commission has determined, on the basis of article 45 of Regional (EU) 2016/679 the country outside the EU offers an adequate level of data protection"</i>. NHS Digital noted that Public Health England (PHE) had requested the inclusion of the special condition and that it was a sound clause and suitable protection to ensure personal data was only ever disseminated to countries with equivalent data protection regimes. However, IGARD members wanted to draw to NHS Digital's attention that this contractual protection did not sit neatly with the special condition in section 6 of the application which meant that only anonymous data will flow under sub licence: <i>"In the interests of transparency CPRD should keep a log of how they have assured themselves that in each instance a sub-licensee is receiving data that has been sufficiently anonymised to render it 'anonymous' and thus outside the scope of GDPR..."</i></p> <p>IGARD also suggested that the special condition in section 6 <i>"CPRD will provide NHS Digital with a confidential copy of the register of customers in receipt of NHS Digital provided data..."</i> be updated to included reference to all COVID-19 related data sets and work along with appropriate justifications including how the data will be kept separate from their other datasets given the different territories of use for each dataset. In addition, IGARD also noted that with regard to this particular special condition that CPRD had committed to provide the original confidential information within one month of the renewal of the DSA and asked if this had been provided and if this had not been provided, that NHS Digital should ensure this special condition is addressed before the application progresses further.</p> <p>NHS Digital noted the ongoing work by the NHS Digital information governance department with regard to legal bases for dissemination of the two additional datasets.</p> <p>IGARD members advised that they would wish to review this application again when it comes up for renewal, extension or amendment.</p> <p>IGARD members suggested that this application would not be suitable for NHS Digital's Precedent route.</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>

