

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 3 December 2020

| IGARD MEMBERS IN ATTENDANCE: | |
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| 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 Lay Chair |
| Dr. Imran Khan | Specialist GP Member |
| IGARD MEMBERS NOT IN ATTENDANCE: | |
| Name: | Position: |
| Dr. Geoffrey Schrecker | Specialist GP Member / IGARD Deputy Specialist GP Chair |
| Dr. Maurice Smith | Specialist GP Member |
| NHS DIGITAL STAFF IN ATTENDANCE: | |
| Name: | Team: |
| Vicky Byrne-Watts | Data Access Request Service (DARS) |
| Lizzie Cherry | Data Access Request Service (DARS) |
| Garry Coleman | Data Access Request Service (DARS) (Observer: item 6.1) |
| Catherine Day | Data Access Request Service (DARS) |
| Arjun Dhillon | Caldicott Guardian (Observer: item 6.1) |
| Louise Dunn | Data Access Request Service (DARS) |
| Joanne Geisler | Data Access Request Service (DARS) (Observer: item 3.5) |
| Dan Goodwin | Data Access Request Service (DARS) |
| Richard Hatton | Clinical Informatics and Deputy Caldicott Guardian (Observer: items 3.1 – 3.4) |
| Karen Myers | IGARD Secretariat |
| Vicki Williams | IGARD Secretariat |
| Guests: | |
| Daniel Smith | General Medical Council (GMC) |

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| 1 | <p>Declaration of interests:</p> <p>Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19.</p> <p>Nicola Fear noted a professional link to the team at NatCen Social Research (NIC-404798-C1Z9R), but noted no specific connection with the application or applicant. In addition, Nicola also noted that as part of her role at King's College London, she required access to the Mental Health of Children and Young People (MHCYP) survey data. It was agreed this did not preclude Nicola from taking part in the discussions about this application, however agreed that she would not participate in making a recommendation about the application.</p> <p>Imran Khan noted a professional link to NIC-218380-R8L2R (Imperial College London) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 26th November 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><u>Sentinel Stroke National Audit Programme (SSNAP) dataset – Briefing Paper (Presenters: Louise Dunn / Lizzie Cherry)</u></p> <p>The Sentinel Stroke National Audit Programme (SSNAP) is a major national healthcare quality improvement programme based in the School of Population Health and Environmental Studies at King's College London. SSNAP measures the quality and organisation of stroke care in the NHS and is the single source of stroke data in England, Wales, and Northern Ireland.</p> <p>The SSNAP data is being onboarded further to the COVID-19 Public Health Directions 2020, 17 March 2020 (as amended) (COVID-19 Direction). This is a Direction to collect and analyse data in connection with COVID-19 to support the Secretary of State's response to COVID-19 and support various COVID-19 purposes. Onboarding the SSNAP data will enable NHS Digital to eventually support COVID-19-related requests for linkage and analysis via Trusted Research Environments (TREs) and Data Access Request Service (DARS) extracts.</p> <p>IGARD welcomed the briefing paper and looked forward to receiving an updated briefing paper alongside a first of type application.</p> <p>IGARD noted that they had previously provided feedback, and supported the onboarding of SSNAP to the suite of datasets in the Clinical Registry dataset in October 2020; and queried how the onboarding of SSNAP described in this briefing paper aligned with the dataset previously supported; and asked that clarification was provided of the interplay between the SSNAP data outlined in the briefing note, and the SSNAP data already onboarded and available in the Clinical Registries Database.</p> <p>In addition, IGARD also asked that confirmation was provided as to which legal basis, the COVID-19 Public Health Directions 2020 or NHS England's other relevant Direction (as</p> |

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| | <p>previously tabled to IGARD), was being relied up on for the collection and dissemination of the SSNAP data for this purpose.</p> <p>IGARD discussed the statement in relation to National Data Opt-outs “...where the data is identifiable, or has been linked and may be considered identifiable in the hands of the user, then the common law duty would be addressed directly and opt-outs may need to be applied.” ; and asked that further consideration be given to whether National Data Opt-outs should be applied.</p> <p>Key points to be addressed in the updated briefing paper:</p> <ol style="list-style-type: none"> 1. To confirm which legal basis (which Direction) is being relied up on for the collection and dissemination of the SSNAP data for this purpose. 2. To clarify the interplay between the SSNAP data outlined in the briefing note, and the SSNAP data already onboarded and available in the Clinical Registries Database. |
| 3 | Data Applications |
| 3.1 | <p><u>University of Oxford: RAPid Testing fOR Covid-19 (RAPTOR-C19) (Presenter: Louise Dunn) NIC-396119-C8W3W</u></p> <p>Application: This was a new application to permit access to data already held or due to flow under NIC-381683-R6R6K (University of Oxford) and NIC-21083-B6C5J (University of Surrey) already stored in the Royal College of General Practitioners Research Surveillance Centre (RCGP RSC), where participants had provided individual patient consent for use of their data as part of ‘Rapid Community Point-Of-Care Testing for COVID-19’ (RAPTOR-C19). The aim is to assess the diagnostic accuracy of multiple current and emerging point-of-care tests (POCTs) for active or past COVID-19 infection in the community setting.</p> <p>The RCGP Research Surveillance Centre (RCGP RSC) was based at the University of Surrey and is in part being transferred to the University of Oxford. The University of Oxford will be the sole Data Controller for this request. The data being shared for the RAPTOR study will be sent to the University of Surrey so that the data can be linked to the RAPTOR cohort and the additional data held by The RCGP RSC.</p> <p>NHS Digital advised IGARD that the application incorrectly referred to the work outlined referred to as a “trial”, and that these references would be removed from the application.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the study.</p> <p>IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 22nd September 2020.</p> <p>IGARD noted the update from NHS Digital, in respect of the incorrect references to the work outlined being a “trial”, and supported the update to the application to remove these references.</p> <p>IGARD noted that section 5(a) (Objective for Processing) contained the list of datasets requested, and asked that this was updated further to provide a clear justification why each of the datasets were being requested, for example, what the benefits are to obtaining this data. In addition, IGARD asked that this was aligned with NHS Digital’s Data Access Request Service (DARS) Objective for Processing Standard.</p> <p>IGARD queried why mortality data was part of the list of datasets requested in section 5(a) and referenced elsewhere in the application. IGARD noted that the purpose of the application did not appear to align with this data being requested and asked that section 5(a) was updated to</p> |

provide a specific justification as to why the mortality data was required. If mortality data was not required, that the application be updated to remove any references to this data.

In addition, IGARD suggested that if mortality data was required, the applicant should update the cohort members of this fact as part of their next communication, for example, in their newsletter, as the current consent materials were silent on this particular point.

IGARD noted that the applicant was requesting 12 years of HES and mortality data, and queried if this was compatible with the participant consent provided and were advised by NHS Digital that following submission of the application to IGARD for review, there had been further discussions with the applicant, who had confirmed that they were now requesting 2 years of historical HES and mortality data. IGARD noted and supported the revised request, and asked that section 3(b) (Additional Data Access Requested) was updated to reflect that two years of historic data was being sought, rather than 12 years.

IGARD queried the information within supporting document 1.1, the adult patient information sheet, that identifiable data would be held for less than 3 months after the study had finished; supporting document 4, the study protocol, stating the end of study would be the last data capture for the last participant for the last test evaluated. IGARD asked that section 5 (Purpose / Methods / Outputs) was updated, with reference to the data capture, to clarify when the study would end.

IGARD noted the reference to the 'Oxford Royal College of General Practitioners Clinical Informatics Hub' (ORCHID) within some of the supporting documents provided, for example supporting document 4, the study protocol, but that this was not referred to within the application; and asked that section 5 was updated to clarify the use of the ORCHID platform.

IGARD noted that following discussion of this application at the IGARD – NHS Digital COVID-19 Response meeting on the 22nd September 2020, and at the IGARD meeting on the 22nd October 2020, where IGARD had provided advice; there had been changes made in terms of the data controllership arrangements. IGARD asked that for ease of reference, and for audit purposes, either a supporting document was provided, or section 1 (Abstract) was updated, with a brief summary of the data controllership arrangements for each of the linked agreements, and the inter-relationship between the agreements.

IGARD queried the reference in section 5(a) to the University of Surrey being joint Data Processors, and asked that this was amended to remove the reference as it was incorrect.

IGARD also noted that section 1 and section 5(b) (Processing Activities) referred to staff being based at the University of Surrey, and asked that this was updated to either amend to reflect the correct information, or to remove the references.

IGARD queried the role of "uMED" with the study, noting that they were referenced within the study protocol, but were not referred to within the application; and asked that section 1 was updated, to include details on the role of uMED.

IGARD noted on the applicant's website, that a future updated ethics approval had been provided for the revised processing but had not been provided as a supporting document, and asked that the application was updated to reflect this. In addition that a copy of the ethics approval was uploaded to NHS Digital's customer relationships management (CRM) system for future reference.

IGARD queried the statement in section 5(a) *"In-context evaluation of POCTs in the community is important as test accuracy can vary based on the prevalence of disease in the*

population tested.”; and asked that this was updated to provide a further explanation of “*in-context*” and ensure that this was in language suitable for a lay reader.

IGARD noted the statement in section 5(a) that related to the ‘COVID-19 National Diagnostic Research and Evaluation Platform’ (CONDOR), and queried if all the information provided was relevant; and if not, asked that the end of the paragraph that started “*its platform design...*” was removed and replaced with a brief statement confirming that CONDOR would not contain any NHS Digital data.

IGARD noted that the two special conditions in section 6 (Special Conditions), relating to the privacy notice and the security assurance, both referenced the Royal College of General Practitioners (RCGP); and noting that the RCGP were **not** involved with the study, asked that the special conditions were updated, to accurately reflect the current data controllership arrangements.

IGARD noted that the postal addresses for the institutions had been listed in sections 1(b) (Data Controller(s)) and 1(c) (Data Processor(s)) rather than the actual processing and storage locations had been entered; and asked that section 1 was updated with the actual physical locations.

IGARD suggested that, in light of the National Institute of Health Research (NIHR) funding for the study, section 5(c) (Specific Outputs Expected) should be updated to clearly outline any earlier patient and public involvement (PPI) engagement. In addition, If there was no PPI engagement planned prior to the result dissemination stage, IGARD strongly suggested that the applicant consider PPI at an earlier stage.

Outcome: recommendation to approve subject to the following conditions:

1. To provide a clear justification in section 5(a) why the datasets are required (which aligns with NHS Digital’s DARS Objective for Processing Standard).
2. In respect of the mortality data requested:
 - a) To update section 5(a) with a specific justification as to why mortality data is required.
 - b) If mortality data is not required, to update the application to remove references to this data.

The following amendments were requested:

1. With reference to data capture, to clarify in section 5 when the study will end.
2. To update section 5 appropriately to reference ORCHID.
3. To either provide a supporting document, or update section 1, with a brief summary of the data controllership arrangements for each of the linked agreements, and the inter-relationship between the agreements.
4. To update section 1 to include details on the role of uMed.
5. To update section 1 and section 5(b) to either amend, or remove, the references to staff based at the University of Surrey.
6. To amend section 5(a) to remove the reference to the University of Surrey being a joint Data Processor.
7. In respect of the recent ethics approval:
 - a) To update the application to reference the recent ethics approval that has been provided for the revised processing.
 - b) To upload a copy of the ethics approval to NHS Digital’s CRM system.
8. To amend section 3(b) to reflect that two years of historic data is being sought, rather than 12.

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| | <ol style="list-style-type: none"> 9. To update the statement in section 5(a) <i>"In-context evaluation of POCTs in the community is important..."</i>, to provide a further explanation of <i>"in-context"</i> and ensure that this is in language suitable for a lay reader. 10. To remove the end of the paragraph in section 5(a) relating to CONDOR that starts <i>"Its platform design..."</i>; and replace with a brief statement confirming that CONDOR will not contain any NHS Digital data. 11. To update the special conditions in section 6, with regards to transparency and security assurance, to accurately reflect the current data controllership arrangements. 12. To update the address details in section 1 with the actual physical locations. 13. To update the application throughout to remove references to <i>"trial"</i>. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that if mortality data was required, the applicant should update the cohort members as part of their next communication, for example, in the newsletter as the current consent materials were silent on this point. 2. IGARD suggested that section 5(c) should be updated to clearly outline any earlier PPI engagement (as may have been required for NIHR funding). 3. If there is no PPI engagement planned prior to the result dissemination stage, IGARD strongly suggested that the applicant consider PPI at an earlier stage. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p> |
| 3.2 | <p><u>Imperial College London: patient choices and provider quality, why patients change GPs (Presenter: Louise Dunn) NIC-218380-R8L2R</u></p> <p>Application: This was a new application for pseudonymised record level extract of England patients listed in the Personal Demographics Service (PDS) dataset data over a 5 year period (2015/16 to 2019/20) to try to understand why an individual moves their GP practice.</p> <p>The research team, based in the Economics and Public Policy Department within the Business School at Imperial College, are requesting data as part of a wider programme of research investigating patient choices over GP providers and the project is looking specifically at how patients choose their GP, and when and why they switch their GP over time, in order to try to understand the factors involved with a change of GP.</p> <p>Discussion: IGARD noted that the application had been updated to reflect most of the comments previously made.</p> <p>IGARD noted that they had previously queried who was funding the study, and that the application was still not clear on this point, and reiterated the request previously made, that section 8(b) (Funding Sources) was updated with the source(s) of the funding.</p> <p>IGARD reiterated their previous comment that the study protocol be updated to provide further meaningful information and background to the study as outlined in the updated application, since it was extremely brief.</p> <p>IGARD reiterated their previous comment with regard to the references throughout the application to <i>"English patients"</i> and queried if, for instance, it referred to those registered with a GPP in England, those who identified as English, or those who lived in England, and asked for further clarity of what was meant by this term in section 5 (Purpose / Methods / Outputs).</p> <p>IGARD noted the references within section 1 (Abstract) to specifically named NHS Digital officials, and the statement that <i>"The study team at Imperial College London will continue to remain in contact with the NHS in order to ensure that the study is as useful as possible"</i>; and asked if there had been any internal endorsement of the proposed study; and asked that NHS</p> |

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| | <p>Digital liaised further with internal colleagues to ascertain if this was a project they would like to actively support.</p> <p>IGARD advised NHS Digital that if colleagues within NHS Digital supported the application (noting the named NHS Digital individuals in section 1), IGARD would be happy to support the project, including working directly with the applicant and NHS Digital to refine the application to meet NHS Digital DARS Standards. Alternatively, IGARD discussed whether it would be an option for the work outlined in the application to be an internal NHS Digital project by the use of an honorary contract, and advised that they would also be supportive of this. However, at this time, IGARD advised NHS Digital, that there were still a number of overarching issues within the application, the main issue being that IGARD were unable to ascertain, clearly, the study goals, and how these goals will promote health or health research, using NHS Digital data.</p> <p>Outcome: Unable to recommend for approval</p> <ol style="list-style-type: none"> 1. NHS Digital to liaise further with internal colleagues to ascertain if this is a project they would like to actively support. 2. If NHS Digital support the application, IGARD would be happy to support the project, be it working directly with the applicant and NHS Digital to refine the application to meet NHS Digital DARS Standards, or supporting an internal project by the use of an honorary contract. 3. To update the source(s) of funding in section 8b. 4. To update the study protocol to provide further meaningful information and background to the study as outlined in the application. 5. To provide further clarity on the references to <i>“English patients”</i> throughout the application and what is meant by this term. |
| 3.3 | <p><u>NHS St Helen's CCG: DSfC - NHS St Helens CCG; RS & IV (Presenter: Dan Goodwin) NIC-47129-G8W4Q</u></p> <p>Application: This was a renewal application for identifiable Secondary User Services (SUS+) data; and an amendment to 1) add Graphnet Health Ltd as a Data Processor for Risk Stratification and using Microsoft Azure Cloud Services; 2) to add Liaison Financial Services Ltd as a Data Processor for Invoice Validation and using Microsoft Azure Cloud Services; 3) to amend any reference to Microsoft UK to Microsoft Limited; 4) to amend the condition surrounding St Helen's and Knowsley NHS Foundation Trust to allow them to access the data; 5) to amend existing CCG addresses to reflect hosting on St Helen's and Knowsley NHS Foundation Trust servers; 6) to amend Arden and GEM Commissioning Support Unit's IT supplier from Oldham CCG to Salford Royal NHS Foundation Trust.</p> <p>The overall purpose is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; and Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care.</p> <p>NHS Digital noted that no yielded benefits had been listed in section 5(d) (Benefits).</p> <p>Discussion: IGARD noted that within the application there were some incorrect references to <i>“John Hopkins”</i>, and asked that the application was updated throughout to correctly refer to <i>“Johns Hopkins”</i>.</p> |

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| | <p>IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be stated and then regularly updated to reflect the work that has been undertaken and the benefits accrued, since the application was last seen by NHS Digital.</p> <p>Separate to this application, IGARD discussed the addition of Graphnet Health Ltd, as a class action, where they are included as a Data Processor on CCG applications (see AOB for further details).</p> <p>IGARD also discussed whether National Data Opt-outs should be applied to risk stratification, in relation to the direct care aspect that may flow from risk stratification; please refer to AOB for further details.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the application throughout to correctly refer to Johns Hopkins. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that when this application comes up for renewal, they would expect the yielded benefits to be clearly outlined, and to reflect the work that has been undertaken, and the benefits accrued since the application was last seen. |
| 3.4 | <p><u>Health Data Research UK R14.2 - CVD-COVID-UK. Cardiovascular disease and COVID-19: using UKwide linked routine healthcare data to address the impact of cardiovascular disease on COVID-19 and the impact of COVID-19 on cardiovascular diseases. (Presenter: Catherine Day) NIC-381078-Y9C5K</u></p> <p>Application: This was an amendment application, to add the following additional pseudonymised datasets to the existing Data Sharing Agreement (DSA), that will be available in the future; 1) Intensive Care National Audit and Research Centre (ICNARC) (linked data); 2) The National Institute for Cardiovascular Outcomes Research (NICOR) – Healthcare Quality Improvement Partnership (HQIP) datasets; 3) NICOR Trans-catheter aortic valve implantation (TAVI) Registry; 4) Stroke Sentinel National Audit Programme (SSNAP); 5) HQIP Commissioned Audit Registry; 6) National Vascular Registry (NVR) HQIP Commissioned Audit Registries; 7) Electronic Prescribing and Medicines Administration (EPMA) Data.</p> <p>The British Heart Foundation (BHF) Data Science Centre, which is embedded within Health Data Research UK (HDR UK), is working in partnership with NHS Digital to establish a Cardiovascular Disease Trusted Research Environment (CVD TRE) [service] for England, to enable analyses of linked, nationally collated healthcare datasets. This project is entitled 'CVD COVID UK', and will enable timely research on the effects/impacts of cardiovascular disease on COVID-19, and the direct and indirect impacts of COVID-19 on cardiovascular diseases; coordinate similar approaches across the four nations of the UK; and future proof an enduring CVD TRE service post-COVID-19.</p> <p>Discussion: IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 26th May, 2nd June, 9th June, 16th June and 23rd June 2020 and suite of documentation had been presented at the IGARD meetings on the 25 June, 23 July and 15 October 2020.</p> <p>IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 24th June 2020, and that notes from this meeting had been attached to the IGARD minutes from the 23rd July 2020.</p> |

IGARD queried which legal basis was being relied upon for the collection, dissemination and use of the SSNAP data, in light of the fact that IGARD had been put on notice that there were two Directions that could be potentially relied on, the COVID-19 Public Health Directions 2020 or NHS England's other relevant Direction (as previously tabled to IGARD); and asked for clarification of this.

IGARD queried what were the expected additional outputs and benefits from the inclusion of the additional datasets requested and asked that, in the absence of this information in the application, that section 5 (Purpose / Methods / Outputs) was updated to clearly set this out. Alternatively, that confirmation was provided in section 5 of how the additional data enriched the existing outputs and benefits.

IGARD also queried the statement in section 5(b) (Processing Activities) *"The BHF Data Science Centre is working in close partnership with NHS Digital to develop a considered and pragmatic approach to data minimisation within the TRE. This work is ongoing"*; and suggested that the application was updated to further reflect the data minimisation and in line with NHS Digital's DARS Standard for Data Minimisation.

IGARD noted the statement in section 4 (Privacy Notice) *"The data controller(s) listed within this agreement in Section 1 (Abstract) confirm that they will ensure that a GDPR compliant, publicly accessible transparency notice is maintained throughout the life of this agreement"*; and noted that that this did not align with the special condition in section 6 (Special Condition): *"A GDPR compliant privacy notice will be published by each data controller within 2 months of signing the DSA."*; and queried if **all** of the controllers had met this condition as it was unclear. IGARD reiterated comments made previously in respect of the NHS Digital policy with regard to privacy notices, that had recently changed from November 2020, IGARD members noted that for those Data Controllers who were party to the agreement prior to the policy change, the special condition would still apply and that appropriate steps should be taken to ensure compliance. IGARD members noted that if the current Data Controllers have met the special condition it would seem reasonable to remove it.

IGARD also asked that the privacy notices for all Data Controller(s) were updated to reflect the joint data controllership arrangements.

ACTION: In light of the outstanding queries in respect of, but not limited to, the privacy notice(s), data controllership and data minimisation, IGARD requested a further discussion with NHS Digital's Associate Director, Data Access.

IGARD noted that the first oversight committee meeting took place on 30th October 2020, and that a quarterly report had been provided as supporting document 7; noting that the information contained within the report was quite minimal, IGARD queried if further details were available and if so, that this be included in section 5.

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 subject to the following condition:

1. To clarify which legal basis is being relied up on for the collection, dissemination and use of the SSNAP data (as IGARD is on notice that there are two Directions that can potentially be relied on).

The following amendments were requested:

1. In respect of the outputs and benefits:

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| | <p>a) To update section 5 to set out the additional outputs and benefits expected from the additional datasets requested; or</p> <p>b) to confirm how this additional data enriches the existing outputs and benefits.</p> <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent. <p>It was agreed the conditions would be approved out of committee (OOC) by IGARD members.</p> |
| 3.5 | <p><u>NatCen Social Research: Patterning of children and young peoples' mental health before and in the context of Covid-19: findings from the 2017 Mental Health of Children and Young People survey and the 2020 MHCYP Covid-19 follow up survey (Presenter: Vicky Byrne-Watts) NIC-404798-C1Z9R</u></p> <p>Application: This was a new application for access to the Mental Health of Children and Young People (MHCYP) survey 2017 and Mental Health of Children and Young People (MHCYP) survey follow up carried out in 2020.</p> <p>The aim of the study is to understand temporal trends and inequalities in mental disorder and service use in children and young people, and the different ways in which symptoms of mental distress and difficulty cluster within a national representative sample of children and young people. This will provide up-to-date evidence using the best sources of data on recent trends in child mental health.</p> <p>This agreement will use the MHCYP survey and 2020 follow up survey of the same children and young people to document the extent to which their mental health has changed during the COVID-19 pandemic. Having an understanding of this distribution pre- and post-pandemic, and how they cluster within sub-groups of the population, can help policymakers and service providers understand the population, deliver support and engagement, and check that they are reaching the relevant groups in the population in the post-COVID context. In addition, assessing the impact of the COVID-19 pandemic on children and young people's mental health will elucidate causal pathways and highlight pathways amenable to intervention to prevent mental health difficulties persisting into adulthood for this generation.</p> <p>Discussion: IGARD noted the statement in section 5(a) (Objective for Processing) that <i>"...Mind have commissioned work on this data..."</i>, and asked that this statement was revised, to more accurately reflect MIND's involvement, otherwise by commissioning the work they could be considered a Data Controller.</p> <p>IGARD noted that NHS Digital had assessed the applicant's Legitimate Interest Assessment (LIA) against the Information Commissioner's Officer (ICO) checklist, as per supporting document 1.0; and noted the statement that <i>"Respondents can opt out at any time"</i>, and asked that the start of section 5(a) was updated, to ensure that the reference to the specific Legitimate Interests was linked to the processing, and as per NHS Digital's DARS Objective for Processing Standard.</p> <p>IGARD noted the benefits outlined in section 5(d) (Benefits), but asked that these were re-ordered from <i>"economic, social and moral"</i> to <i>"social, moral and economic"</i> benefits. In addition, IGARD commended the applicant for recognising and outlining the moral obligations in section 5(d).</p> |

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| | <p>IGARD noted the reference in section 1 (Abstract) to the Adult Psychiatric Morbidity Survey (APMS) and asked that these references were removed as they were not relevant to this application.</p> <p>IGARD suggested that <i>if</i> the applicant had worked with the Anna Freud Centre, which is an advocate for children's mental health, and as referenced in the specification for the Direction underlying the data collection, that the applicant include reference to them in section 5 (Purpose / Methods / Outputs).</p> <p>IGARD advised that separate to this application, at the IGARD meeting on the 26th November 2020, IGARD had received a number of supporting documents in respect of the Mental Health of Children and Young People (MHCYP) survey data, and had provided comments.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5(a) to revise the statement that MIND has "<i>commissioned</i>" this work. 2. To update section 5(a) to ensure reference to the specific Legitimate Interests as linked to the processing as per NHS Digital's DARS Objective for Processing Standard. 3. To revise section 5(d) to ensure that the benefits are re- ordered: "<i>social, moral and economic</i>". 4. To amend section 1 to remove references to the APMS. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that <i>if</i> the applicant had worked with the Anna Freud Centre, which is an advocate for children's mental health – and as referenced in the specification for the Direction underlying the data collection - that the applicant include reference to them in section 5. |
| 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> <ul style="list-style-type: none"> • NIC-148022-1MQBH University of Newcastle • NIC-375354-G8V1H University of Oxford • NIC-382334-Y2B1C National Audit Office • NIC-396423-H4Z6Z University of Oxford <p>IGARD welcomed the four 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 The Health Service Control of Patient Information (COPI) Regulations 2002 applications may also be included as part of the oversight and assurance review, not just those that were approved via NHS Digital's precedent route.</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</p> |

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| | <p>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 1st December 2020 can be found attached to these minutes as Appendix C.</p> |
| 6 | <p><u>AOB:</u></p> |
| 6.1 | <p><u>Graphnet Health Ltd</u></p> <p>NHS Digital asked if consideration could be given to where Graphnet Health Ltd is being included as a Data Processor on CCG applications, this could be done by way of notification to IGARD for inclusion on the out of committee (OOC) report appended to published minutes, in the same way that Liaison Financial Services (referred to as 'Liaison') and Optum Health Solutions UK Limited (referred to as 'Optum') inclusion is notified. IGARD were content with this approach to include the NIC number and organisation in the OOC report in respect of Optum, Liaison and Graphnet Health Ltd.</p> |
| 6.2 | <p><u>National Data Opt-outs for risk stratification</u></p> <p>IGARD discussed whether National Data Opt-outs should be applied to risk stratification, in relation to the direct care aspect that may flow from risk stratification agreed that a further workshop would be arranged to discuss this in further detail.</p> |
| 6.3 | <p><u>General Medical Council (GMC) - UK Medical Education Database (UKMED) (Presenter: Daniel Smith)</u></p> <p>As part of IGARD's education agenda, a representative from the GMC attended to present further information on the UKMED, which is a longitudinal dataset for medical education research.</p> <p>The IGARD Chair welcomed the presentation on behalf of the members present, and thanked Daniel for attending.</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 27/11/20

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) |
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| NIC-400304-S1P1B - | Office for National Statistics | 19/11/2020 | <ol style="list-style-type: none"> 1. In respect of the ethical approval, to either: <ol style="list-style-type: none"> a) Provide written evidence that a positive Ethics opinion has been sought; or; b) Provide written confirmation that the data ethics advisory committee is satisfied that an updated opinion is not required; c) To upload a copy of the ethics approval; or a suitable response from Ethics confirming that updated ethics approval is not required, to NHS Digital's CRM system. | IGARD members | IGARD Chair, under Chair's Authority | <p>Feedback from IGARD Chair:</p> <p><i>"Noting that we did not receive the requisite three positive responses, this condition has not been met.</i></p> <p><i>However, I am prepared to take chair's action and set aside that condition, replacing with the following: "Suitable confirmation that updated ethics approval is not required". I am content that that amended condition has been met.</i></p> <p><i>Notwithstanding the above confirmation, as and when future data sets or purposes are added to this project, I would expect contact to be made with the Ethics</i></p> |

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| | | | | | | <i>Committee directly for them to expressly confirm that they do not consider there is a need to refresh or review their opinion (or to review and issue a refreshed opinion)."</i> |
| NIC-135277-R8M3G | Regional Drug & Therapeutic Centre | 17/11/2020 | 1. In respect of the PAG comments: <ol style="list-style-type: none"> To confirm that PAG at their meeting on 28th October received the updated application which addressed the points raised at the 7th October PAG meeting; or if not the case, the revised application be presented to PAG and they confirm, in writing, that they are content with responses received | IGARD Chair | IGARD Chair | None |

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

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

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-134613-G2M6G NHS Northumberland CCG
- NIC-36892-P3B3F NHS Sunderland CCG

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, 1st December 2020

In attendance (IGARD Members): Prof Nicola Fear (Specialist Academic Member)

Kirsty Irvine (IGARD Lay Chair)

In attendance (NHS Digital):

Dave Cronin (DARS)

Cath Day (DARS)

Louise Dunn (DARS)

Duncan Easton (DARS)

James Gray (DARS)

Karen Myers (IGARD Secretariat)

Heather Pinches (DARS)

Andy Rees (DARS)

Charlotte Skinner (DARS – observer)

Kimberley Watson (DARS)

Vicky Byrne-Watts (DARS)

Vicki Williams (IGARD Secretariat)

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| 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 any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix.</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 on COVID-19.</p> |
| 2.1 | <p><u>Oxford RECOVERY Trials (NIC Number unknown)</u></p> <p>Background: This was a verbal update to verbal and application presentations at the 28th April, 5th May, 12th May, 19th May, 7th July, 21st July, 22nd September and 20th October COVID-19 response meetings.</p> <p>A draft Data Sharing Sub Licence had been provided for consideration which outlined a number of key areas including the purpose for data sharing, governance of access to the data, legal basis, data content controls for release of data, data context controls for release of data,</p> |

transparency, territory, reporting and breaches, audit and termination. It is intended that the RECOVERY Trial onwardly shares data for a limited number of purposes and this discussion was in advance of any formal discussion at an IGARD business as usual (BAU) meeting.

The following observations were made on the basis of the verbal briefing and draft sub-licensing document only.

IGARD Observations:

IGARD members suggested that since GPES Data for Pandemic Research & Planning (GDPPR) data was included, that DARS discuss the proposed sub-licensing agreements with the Profession Advisory Group (PAG). As arrangements currently stand, when the CV-19 Direction (issued under the emergency National Health Service (Control of Patient Information Regulations) 2002 (COPI)) expires at some point in the future, the data would have to be destroyed.

IGARD members made a number of key points with reference to the draft sub licensing document including, but not limited to:

- To ensure the document aligned with NHS Digital's policy position for sub-licensing by referring to the detailed NHS Digital's DARS Standard for Sub Licencing and Onward Sharing of Data. If the parties agreed to depart from that Standard, to clarify why that departure was required.
- To define "Data Protection Law".
- To ensure incorporation by reference of such items as the contractual terms of the Applicant's Data Sharing Framework Contract (DSFC) and Data Sharing Agreement (DSA).
- To consider whether necessary public safety access for Regulatory Authorities and Manufacturers could be addressed by permissive contractual terms in the DSA or DSFC, rather than by sublicence.
- To set out clear parameters for the research, or if not possible, to set out guiding principles in the governance body terms of reference.
- Further consideration should be given to transparency, referring to NHS Digital's DARS Standard for Transparency, to ensure that there were "no surprises" for the consented cohort (see paragraph one of the Standard for Sub Licencing and Onward Sharing of Data), as well as ongoing compliance with GDPR.
- Any governance arrangements should be clearly set out (referring to the NHS Digital DARS Standard for Sub Licencing and Onward Sharing of Data and Standard for Data Minimisation); such as a relevant governance committee, terms of reference, how the sub licensing addresses the benefits to and/or promotes health or social care.
- Consideration should be given to any commercial aspects to the sub-licensing and this should be in line with the published NHS Digital DARS Standard for Commercial Purpose and again reflected in the governance terms of reference.
- The legal basis outlined should link back to that set out in NHS Digital DARS Standard for Sub Licencing and Onward Sharing of Data.

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| | <ul style="list-style-type: none"> • IGARD suggested that using existing sub licencing documents used by other users of NHS Digital data as a template may be an expedient place to start and suggested any contractual arrangements should be discussed with NHS Digital's legal department. • The audit section outlined should also link back to NHS Digital DARS Standard for Sub Licencing and Onward Sharing of Data, including the reporting of breaches. |
| 2.2 | <p><u>NIC-402417-N9Z5W UCL Partners</u></p> <p>Background: This was a brief verbal update to the update received on the COVID-19 response meeting 6th October, 13th October and 10th November 2020 with regard to the NHS Digital Cancer Trusted Research Environment (TRE) and an application from UCL Partners to access the Cancer TRE.</p> <p>The following observations were made on the basis of the verbal briefing only.</p> <p>IGARD Observations:</p> <p>NHS Digital noted that further discussions were being undertaken between all parties involved in the Cancer TRE which was supporting the work being undertaken to scope specific applications.</p> <p>IGARD members thanked NHS Digital for the update and looked forward to receiving more information in due course.</p> |
| 2.3 | <p><u>NIC-413717-C8Y6K Office for National Statistics (ONS)</u></p> <p>Background: The application had previously been considered for advice at the IGARD business as usual (BAU) meeting on the 20th November 2020 and at the time IGARD members had noted their support for the application. Due to the urgency of the request, the application had been updated and proceeded via the SIRO precedent.</p> <p>IGARD Observations:</p> <p>IGARD members noted the update from NHS Digital and reiterated their support for the application.</p> <p>IGARD members noted the verbal update from NHS Digital with regard to Data Controllership, and suggested that this further detailed analysis was also articulated in section 1, for future reference, as to why the University of Oxford were not considered a joint Data Controller.</p> <p>IGARD members also noted that NHS Digital had undertaken a full review of all the consent materials, and suggested that a brief summary of this exercise be included in section 1 outlining the review and outcome, for future reference.</p> |
| 2.4 | <p><u>NIC-418208-J1Y6J – Pharm-Olam</u></p> <p>Background: This was a verbal update outlining a Phase I/II randomised, two parts, dose-finding study to evaluate the safety, tolerability and immunogenicity of an inactivated, adjuvanted SARS-COV-2 virus vaccine candidate (VLA2001) against COVID-19 in healthy subjects.</p> <p>The following observations were made on the basis of the verbal briefing only.</p> <p>IGARD observations:</p> |

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| | <p>IGARD members noted the brief overview of the draft application and suggested that it be clearly articulated in all documentation (communications with the Permission to Contact cohort) and the application that this was a phase I/II randomised trial to ensure that participants were clear from the onset that these were early stage trial vaccines and that it would (presumably) preclude them from taking part in other vaccine trials, including phase III vaccine trials.</p> <p>IGARD members also suggested that the application could also outline all three phases of the study, with a clear delineation between each phase in order to allow the same application to be relied on for receipt of details for further potential cohort members as the study progressed.</p> <p>Noting that for phase I the applicant was seeking 15 participants and for phase II they were seeking 135 in the age range 18 to 55, IGARD members queried the use of the Permission to Contact (PtC) database. NHS Digital explained that the PtC database had currently over 400,000 participants and were content with the approach and that it was the most expedient way of quickly assembling a suitable cohort. IGARD agreed.</p> |
| 2.5 | <p><u>NIC-381683-R6R6K University of Oxford (PHE / RCGP)</u></p> <p>Background: This was an update to an application presented to the business as usual (BAU) IGARD meeting on the 27th August 2020. The application had been previously recommended for approval subject to a number of conditions in relation to the data flows and NHS Digital had brought it back due to the changes made to the application and the time elapsed since IGARD's recommendation.</p> <p>IGARD Observations:</p> <p>IGARD members noted this was a BAU application. IGARD members noted the update from NHS Digital and that conditions for returning to IGARD for review out of committee had fallen outside of the agreed 3 month timeframe. IGARD members were content that significant work had been undertaken by the applicant and that on this occasion the application and associated documentation, once updated with an explanation of the developments, would still be able to be submitted out of committee for review (following the BAU process).</p> |
| 2.6 | <p><u>NIC-411813-H0T2W Wellcome Sanger Institute</u></p> <p>Background: this was an update to the COVID-19 response meeting on the 10th November 2020. The draft application was from the Wellcome Sanger Institute (funded by the Wellcome Trust), in relation to the sequencing as part of the COVID-19 genomic sequencing work and access to Pillar 2 testing data in order to pick up positive test results in order to support the wider health system in spotting potential "super spreaders" or outbreaks in a region.</p> <p>NHS Digital noted that the security arrangements were still outstanding along with a signed Data Sharing Framework Contract (DSFC) and that further work was being undertaken to put appropriate arrangements in place.</p> <p>The following observations were made on the basis of the draft application only.</p> <p>IGARD Observations:</p> <p>IGARD members reiterated their previous comments that DARS be clear as to who was/were the Data Controller/s under the agreement, citing the NHS Digital DARS Standard for Data Controllers / Data Processors, and that this should be borne out by the facts presented. In addition, and noting the update from NHS Digital with regard to funding received from various</p> |

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| | <p>sources, that the funding arrangements should be clearly articulated within section 5 of the application for transparency and funding agreements (if available) be tabled to NHS Digital and loaded to CRM.</p> <p>Noting the work across the four devolved nations, IGARD members also suggested that more information about this work be included in section 5, which would also draw out the funding arrangements in place and the work ongoing with the Department of Health & Social Care and Public Health agencies across the devolved nations.</p> <p>IGARD members reiterated their previous comments with regard to specimens the applicant was receiving from PHE and if they were swabs, which would contain human DNA, or petri dishes (for example) with parts of the human DNA and raised the potential legal and ethical issues around sharing human DNA without consent (not least that that human DNA could be classed as personal data under the General Data Protection Regulation (GDPR)). NHS Digital confirmed that only virus DNA sequence would be linked to any data from NHS Digital, however the samples may be sent to any of the four devolved nations in the United Kingdom for analysis and that further information had been included in section 5.</p> <p>IGARD members noted that section 5 should be updated in a language suitable for a lay reader and that consideration is given to a patient audience (for example when referring to “<i>vaccine evasion</i>”); reference to the data fields be removed, such as “CH1” etc and instead referenced correctly in the data minimisation column in section 3b; and reference to “<i>outer postcode</i>” be updated to more accurately reflect the first four digits of the postcode. IGARD members also noted reference in section 5(d) to “...<i>analysis in the post-winter peak phase of the pandemic to keep it as calm as possible for as long as possible...</i>” and suggested this be quantified as a statement.</p> <p>IGARD members noted reference in section 5c to the “<i>MRC-CLIMB database</i>” which is a cloud based storage solution and accessed by UK researchers and international partners, and suggested that further information be with regard to the role of the MRC and who had access to the data.</p> <p>IGARD members noted that the applicant was referred to as both the Wellcome Sanger Institute and Genome Research Limited, wholly owned subsidiary of the Wellcome Trust, and suggested that a clear statement of fact be included in section 1 of the entities involved and that the correct entity be clearly referenced throughout the application.</p> <p>IGARD members noted that section 7 had not been completed and referenced ethics as “<i>Ethics approval is not required because</i>” and suggested that this section was updated, as appropriate.</p> <p>IGARD members queried why the application was not considered having any commercial aspect and suggested that the facts be quantified and linked to the NHS Digital DARS Standard for Commercial Purpose.</p> <p>IGARD members noted the update from NHS Digital with regard to the DSFC contract not having been signed and that the security arrangements for the Data Controller and Data Processor remained outstanding.</p> |
| 2.7 | <u>NIC-339727-Y2H8M Royal College of Surgeons (RCGP) in Ireland</u> |

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| | <p>Background: This was a business as usual (BAU) application that had been brought for a formal review and advice on the consent and patient information materials.</p> <p>The study aims to inform on the complications, short and long term outcome of arthroscopic anterior cruciate ligament reconstruction.</p> <p>IGARD Observations:</p> <p>IGARD members noted this was a BAU application. IGARD members noted that due to the quick turn-around, quoracy and nature of this COVID-19 response meeting, they were not able to undertake a BAU formal review and advice on the consent and patient information materials.</p> <p>NHS Digital explained that the applicant had been asked by NHS Digital to apply to the Health Research Authority Confidentiality Advisory Committee (HRA CAG) for s251 support and that CAG had advised that the consent had been obtained from 2011 onwards and was relatively generic and of its time but that the activity would not likely be a surprise to the participants, suggested that a newsletter could be used to augment the old consent material. NHS Digital proposed that this draft newsletter along with the usual suite of documentation could be presented to a future IGARD BAU meeting for a formal review. IGARD members agreed with this analysis and approach, noting that CAG was the final arbiter on whether the duty of confidentiality had been satisfied.</p> <p>IGARD members also noted that the application would need to be updated to reflect the current suite of NHS Digital DARS standards, including further consideration being given to the data being disseminated to the Republic of Ireland.</p> <p>IGARD members suggested that, given the history, NHS Digital may wish to prioritise this application on the BAU agenda in order to support the applicant.</p> |
| 2.8 | <p><u>NIC-404798-C1Z9R NatCen Social Research</u></p> <p>Background: This was a new application from the National Centre for Social Research (NatCen) for 2017 Mental Health of Children & Young People Survey and 2020 Mental Health & Young Children COVID-19 follow up survey. The survey series provides England's best source of data on trends in child mental health issues.</p> <p>IGARD Observations:</p> <p>IGARD members noted that the application was to be presented to the IGARD business as usual (BAU) Meeting on Thursday, 3rd December 2020. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.</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> |