**Independent Group Advising on the Release of Data (IGARD)**

**Minutes of meeting held via videoconference 2nd April 2020**

**In attendance (IGARD Members):** Paul Affleck, Maria Clark, Kirsty Irvine (Chair), Imran Khan, Geoffrey Schrecker, Maurice Smith.

**In attendance (NHS Digital):** Stuart Blake, Dave Cronin, Louise Dunn, Karen Myers, Bethan Thomas, Kimberley Watson, Vicki Williams.

**Not in attendance (IGARD Members):** Nicola Fear.

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| **1** | **Declaration of interests:**<br>There were no declarations of interest.<br>**Review of previous minutes and actions:**<br>The minutes of the 26th March 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.<br>**Out of committee recommendations:**<br>An out of committee report was received (see Appendix B). |
| **2** | **Data Applications** |
| **2.1** | University of York: MR1325 - Yorkshire and Humberside Haematology Network Register (YHHN) Comparison Cohort (Presenter: Louise Dunn) NIC-06759-X5V7P<br>**Application:** This was a renewal application for pseudonymised Medical Research Information Service (MRIS), Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) data; and two amendments to 1) add Hull and East Yorkshire Hospital NHS Trust as a joint Data Controller; and 2) a request to receive Lower Super Output Area (LSOA) data. The purpose is to maintain and update the Yorkshire and Humberside Haematology Network's (YHHN) comparison cohort. The overall aim is to facilitate a greater understanding of the causes of haematological cancers, as well as their impact on the future health and healthcare needs of those who develop them.<br>NHS Digital advised IGARD that this application was one of three linked applications, the others being NIC-390749-C4P0X (Item 2.2) and NIC-346859-C9J6J (Item 2.3) and that this application provided a national control cohort for the study. NHS Digital outlined that the patient cohort in application NIC-390749-C4P0X was covered by consent and the patient cohort in application NIC-346859-C9J6J, who were deemed too ill to provide consent, were covered by Section 251 of the NHS Act 2006.<br>NHS Digital also advised that section 3(b) (Additional Data Access Requested) noted that the data requested was 'identifiable', however confirmed this was an internal processing issue, and confirmed that the data was pseudonymised.<br>**Discussion:** IGARD thanked the presenter and noted the update provided by NHS Digital outlining how the three applications were linked; and that the data requested was pseudonymised and not identifiable.<br>IGARD queried the cohort sizes for all three applications that were referred to within this application, noting that the cohort number were not consistent and did not tally with documentation provided; and asked that the application was amended to ensure that the cohort sizes referred to were accurate and consistent with the other linked applications. |

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| | In addition, IGARD also queried what the justification was for creating a national control cohort and asked that section 5(a) Objective for Processing was updated with a justification for this.<br><br>IGARD noted that text in the three linked applications was not consistent, for example when describing the purpose, and asked that the text in this application was aligned with the other applications to ensure there was no inconsistencies.<br><br>IGARD noted the amendment within the application in relation to the data controllership and queried if the Health Research Authority Confidentiality Advisory Group (HRA CAG) and the relevant Ethics Committee had been made aware of all the parties involved with this project, and asked that written confirmation was provided.<br><br>IGARD noted the s251 support for application NIC-346859-C9J6J and asked that section 5(a) was updated to make reference to this and to provide a further explanation of why and what the s251 was required for in relation to this application.<br><br>IGARD queried if the funding described in the application and the supporting documents was ongoing, noting that this information had not been clarified; and asked that written evidence was provided confirming this.<br><br>IGARD noted that the applicant was requesting Lower Super Output Area (LSOA) data and Census Output area, and queried why the applicant required both sets of data and asked that further justification of why the applicant required the additional Census Output Area was provided.<br><br>IGARD noted the reference in section 3(b) to the Information Commissioner's Office (ICO) Code of Practice and asked that this was removed or amended in line with a form of wording agreed with NHS Digital Information Governance (IG).<br><br>IGARD queried the reference in section 5(c) (Specific Outputs Expected) to *"Data will only be accessed and processed by substantive employees of University of York and Hull and East Yorkshire Hospitals Trust"*, noting that only the University of York was processing the data, IGARD asked that this was amended to remove reference to *"Hull and East Yorkshire Hospitals Trust"*.<br><br>IGARD noted the references within the application to the Hull University Teaching Hospitals NHS Trust Data Security and Protection Toolkit (DPST) action plan, and asked that confirmation was provided advising if this had been completed and that there were no outstanding action points.<br><br>In addition, IGARD asked that the special condition outlined in section 6 (Special Conditions) in relation to Hull University Teaching Hospitals NHS Trust's DSPT was removed if this had now been satisfied.<br><br>IGARD noted the excellent Patient and Public Involvement (PPI) outlined in the HRA CAG supporting material and asked that this was also replicated in section 5(c) of the application.<br><br>IGARD noted that when this application was last reviewed by IGARD's predecessor the Data Access Advisory Group (DAAG) in 2016, DAAG advised that a newsletter was sent to the study participants, with a number of points that could be addressed, for example planned data processing. IGARD asked that confirmation was provided if a newsletter had been circulated; and if not, to insert a special condition in section 6 replicating the previous DAAG advice with an appropriate timeframe for this to be completed.<br><br>IGARD noted and endorsed NHS Digital's review that Yorkshire & Humberside Haematology Network did **not** meet NHS Digital's Standard for privacy notices. |

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| | IGARD suggested that the statement in section 5(a) that stated *"…there are no moral or ethical issues…"* was removed since it was not necessary to include in the application.<br><br>**Outcome Summary:** recommendation to approve subject to the following conditions:<br><br>1. To provide written confirmation that both HRA CAG and the relevant Ethics Committees are aware of all the parties involved with the project.<br>2. To provide written evidence that the funding as described in the application and supporting documents is ongoing.<br>3. To provide justification of why the Census Output Area has been requested in addition to the Lower Super Output Area data requested.<br><br>The following amendments were requested:<br><br>1. To amend the application to ensure that the cohort sizes referred to within this application are accurate and that the cohort numbers are consistent across all the other linked applications (NIC-390749-C4P0X and NIC-346859-C9J6J).<br>2. To align the text in this application with the other the linked applications to ensure there are no inconsistencies (NIC-390749-C4P0X and NIC-346859-C9J6J).<br>3. To remove reference to the ICO Code of Practice from section 3(b) and / or amend in line with a form of wording agreed with NHS Digital IG.<br>4. To amend section 5(c) to remove reference to Hull and East Yorkshire Hospitals Trust processing or accessing the data.<br>5. To provide confirmation that the DSPT action plan has been completed and that there are no outstanding points.<br>6. To update section 5(a) to make reference to and explain the s251 support.<br>7. To update section 5(a) to provide justification for the creation of the national control cohort.<br>8. To replicate the PPI information outlined in the HRA CAG supporting materials in section 5(c).<br>9. To amend section 6 to remove the special condition that has now been satisfied with regard to Hull University Teaching Hospitals NHS Trust.<br>10. To confirm if a newsletter to the study participants has been circulated; and if not, to insert a special condition in section 6 replicating the previous DAAG advice with an appropriate timeframe for this to be completed.<br>11. To remove from section 5(a) reference to '*there are no moral or ethical issues*".<br><br>It was agreed the condition would be approved Out of Committee (OOC) by IGARD members. |
| **2.2** | <u>University of York: MR1126a - Yorkshire and Humberside Haematology Network (YHHN) (Presenter: Louise Dunn) NIC-390749-C4P0X</u><br><br>**Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) data; and an amendment to add Hull University Teaching Hospitals NHS Trust as a joint Data Controller. The purpose is to maintain and update the Yorkshire and Humberside Haematology Network's (YHHN) comparison cohort. The overall aim is to facilitate a greater understanding of the causes of haematological cancers, as well as their impact on the future health and healthcare needs of those who develop them.<br><br>NHS Digital advised IGARD that this application was one of three linked applications, the others being NIC-06759-X5V7P (Item 2.1) and NIC-346859-C9J6J (Item 2.3) and that this application had a patient cohort for the study that was covered by consent. NHS Digital outlined that the application NIC-06759-X5V7P provided a national control cohort for the study |

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| | and the patient cohort in application NIC-346859-C9J6J, who were deemed too ill to provide consent were covered by Section 251 of the NHS Act 2006.<br><br>NHS Digital also advised that section 3(b) (Additional Data Access Requested) noted that the data requested was 'identifiable', however this was an internal processing issue, and confirmed that the data was pseudonymised.<br><br>**Discussion:** IGARD thanked the presenter and noted the update provided by NHS Digital outlining how the three applications were linked; and that the data requested was pseudonymised and not identifiable.<br><br>IGARD queried the cohort sizes for all three applications that were referred to within this application, noting that the cohort number were not consistent and did not tally with documentation provided; and asked that the application was amended to ensure that the cohort sizes referred to were accurate and consistent with the other linked applications.<br><br>IGARD noted that some members of the cohort were consented before 2009, and asked what communication that had been issued to those members of the cohort and if they been made aware of the flow of data to NHS Digital, and asked for confirmation of this. IGARD asked that if there had been no communication advising the cohort members (recruited prior to 2009), that confirmation was provided, of how this would be addressed, for example by way of a newsletter. IGARD noted that NHS Digital's standard on Duty of Confidentiality stated that where consent is considered insufficient the applicant should take appropriate measures to make information available by way of additional patient information for anyone consented prior to 2009, thereby improving transparency and giving individuals the option to withdraw consent.<br><br>IGARD also noted that some members of the cohort gave consent when they were under the age of 16 and asked for clarification of how the applicant was addressing those members who were now over the age of 16, for example communicating with them to advise how they could withdraw from the study.<br><br>IGARD noted that text in the three linked applications was not consistent, for example when describing the purpose, and asked that the text in this application was aligned with other applications to ensure there was no inconsistencies.<br><br>IGARD noted the amendment within the application in relation to the data controllership and queried if the Health Research Authority Confidentiality Advisory Group (HRA CAG) and the relevant Ethics Committee had been made aware of all the parties involved with this project, and asked that written confirmation was provided.<br><br>IGARD noted the s251 support for application NIC-346859-C9J6J and asked that section 5(a) (Objective for Processing) was updated to make reference to this and to provide a further explanation of why and what the s251 was required in relation to this application.<br><br>IGARD queried if the funding described in the application and the supporting documents was ongoing and noted reference to the National Institute for Health Research (NIHR) and Leeds Teaching Hospitals NHS Trust within supporting document 18 which showed a payment schedule in particular to Leeds Teaching Hospitals NHS Trust and since they were not listed in the application asked that written evidence was provided confirming the funding arrangements in place.<br><br>IGARD queried the reference in section 5(c) (Specific Outputs Expected) to *"Data will only be accessed and processed by substantive employees of University of York and Hull and East Yorkshire Hospitals Trust"*, noting that only the University of York was processing the data, IGARD asked that this was amended to remove reference to *"Hull and East Yorkshire Hospitals Trust"*. |

IGARD queried the reference in section 5(a) that stated *"all patients resident in the study"* and queried if this referred to just the consented cohort or those included by way of s251 support, and asked that further clarification was provided.

IGARD noted the excellent Patient and Public Involvement (PPI) outlined in the HRA CAG supporting material and asked that this was also replicated in section 5(c) of the application.

IGARD noted and endorsed NHS Digital's review that Hull University Hospitals NHS Trust did **not** meet NHS Digital's Standard for privacy notices.

IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.

**Outcome Summary:** recommendation to approve subject to the following conditions:

1. For those members of the cohort consented before 2009:
   a) To confirm what communication has been issued to those members of the cohort and if those members of the cohort were made aware of the flow of data to NHS Digital.
   b) If there has been no communication advising them of the flow of data to NHS Digital, to provide confirmation of how this will be addressed for example by way of a newsletter communication to the relevant section of the cohort.
2. For those members of the cohort under the age of 16 years at the time of consent, to clarify how the applicant is addressing those members now they are over the age of 16, for example communicating with them advising of how they can withdraw from the study.
3. To provide clarification of the funding arrangement for this application, in particular in relation to supporting document 18, which shows a payment schedule to Leeds Teaching Hospitals NHS Trust.
4. To provide written confirmation that both HRA CAG and the relevant Ethics Committees are aware of all the parties involved with the project.

The following amendments were requested:

1. To amend the application to ensure that the cohort sizes referred to within this application are accurate and that the cohort numbers are consistent across all the other linked applications (NIC-06759-X5V7P and NIC-346859-C9J6J).
2. To align the text in this application with the other linked applications to ensure there are no inconsistencies (NIC-06759-X5V7P and NIC-346859-C9J6J).
3. To update section 5(a) to make reference to and explain the s251 support.
4. To amend section 5(c) to remove reference to Hull and East Yorkshire Hospitals Trust processing or accessing the data.
5. To provide further clarification on the statement in section 5(a) "*all patients resident in the study"* and if this refers to just the consented cohort or those included by way of s251 support.
6. To replicate the PPI information outlined in the HRA CAG supporting materials in section 5(c)

The following advice was given:

1. IGARD suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.

It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.

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| **2.3** | University of York: MR1126b - Yorkshire and Humberside Haematology Network (YHHN) (Presenter: Louise Dunn) NIC-346859-C9J6J<br><br>**Application:** This was a renewal application for pseudonymised Medical Research Information Service (MRIS), Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS) data; and an amendment to add Hull University Teaching Hospitals NHS Trust as a joint Data Controller. The purpose is to maintain and update the Yorkshire and Humberside Haematology Network's (YHHN) comparison cohort. The overall aim is to facilitate a greater understanding of the causes of haematological cancers, as well as their impact on the future health and healthcare needs of those who develop them.<br><br>NHS Digital advised IGARD that this application was one of three linked applications, the others being NIC-390749-C4P0X (Item 2.2) and NIC-06759-X5V7P (Item 2.1) and that this application was for the patient cohort too ill to provide consent and were therefore covered by Section 251 of the NHS Act 2006. NHS Digital outlined that the application NIC-06759-X5V7P provided a national control cohort for the study and NIC-390749-C4P0X had a patient cohort for the study that was covered by consent.<br><br>NHS Digital also advised that section 3(b) (Additional Data Access Requested) noted that the data requested was 'identifiable', however this was an internal processing issue, and confirmed that the data was pseudonymised.<br><br>NHS Digital advised that the applicant's Health Research Authority Confidentiality Advisory Group (HRA CAG) review had expired and were awaiting confirmation from the applicant confirming that that this had been submitted for renewal.<br><br>**Discussion:** IGARD thanked the presenter and noted the update provided by NHS Digital outlining how the three applications were linked; and that the data requested was pseudonymised and not identifiable. IGARD also noted that the applicants HRA CAG annual review was due and asked that confirmation was provided confirming that this had been submitted.<br><br>IGARD queried the cohort sizes for all three applications that were referred to within this application, noting that the cohort number were not consistent; and asked that the application was amended to ensure that the cohort sizes referred to were accurate and consistent with the other linked applications.<br><br>IGARD noted that text in the three linked applications was not consistent, for example when describing the purpose, and asked that the text in this application was aligned with other applications to ensure there was no inconsistencies.<br><br>IGARD noted the s251 support for this application and asked that section 5(a) (Objective for Processing) was updated to make reference to this and to provide a further explanation of why and what the s251 was required in relation to this application.<br><br>IGARD queried the reference in section 5(c) (Specific Outputs Expected) to *"Data will only be accessed and processed by substantive employees of University of York and Hull and East Yorkshire Hospitals Trust"*, noting that only the University of York was processing the data, IGARD asked that this was amended to remove reference to *"Hull and East Yorkshire Hospitals Trust"*.<br><br>IGARD noted the amendment within the application in relation to the data controllership and queried if the Health Research Authority Confidentiality Advisory Group (HRA CAG) and the relevant Ethics Committee had been made aware of all the parties involved with this project, and asked that written confirmation was provided. |

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| | IGARD queried if the funding described in the application and the supporting documents was ongoing, noting that this information had not been clarified; and asked that written evidence was provided confirming this.<br><br>IGARD noted the excellent Patient and Public Involvement (PPI) outlined in the HRA CAG supporting material and asked that this was also replicated in section 5(c) of the application.<br><br>IGARD noted and endorsed NHS Digital's review that Hull University Hospitals NHS Trust did **not** meet NHS Digital's Standard for privacy notices.<br><br>**Outcome Summary:** recommendation to approve subject to the following conditions:<br><br>1. To provide written confirmation that both HRA CAG and the relevant Ethics Committees are aware of all the parties involved with the project.<br>2. To provide written evidence that the funding as described in the application and supporting documents is ongoing.<br><br>The following amendments were requested:<br><br>1. To amend the application to ensure that the cohort sizes referred to within this application are accurate and that the cohort numbers are consistent across all the other linked applications (NIC-390749-C4P0X and NIC-06759-X5V7P).<br>2. To align the text in this application with the other the linked applications to ensure there are no inconsistencies (NIC-390749-C4P0X and NIC-06759-X5V7P).<br>3. To update section 5(a) to make reference to and explain the s251 support.<br>4. To amend section 5(c) to remove reference to Hull and East Yorkshire Hospitals Trust processing or accessing the data.<br>5. To provide confirmation that the HRA CAG annual review has been submitted.<br>6. To replicate the PPI information outlined in the HRA CAG supporting materials in section 5(c)<br><br>It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members. |
| **2.4** | <u>Northumbria Healthcare NHS Foundation Trust: The NIVO Study: Readmission and Mortality to one year after discharge from hospital. (Presenter: Dave Cronin) NIC-249035-R2Z5Y</u><br><br>**Application:** This was a new application for identifiable Hospital Episodes Statistics (HES) and Civil Registrations data. The purpose is for The Non-Invasive Ventilation Outcomes (NIVO) Study, a 10-centre prospective trial, assessing outcomes in hospital and after discharge in patients who are ventilated for exacerbations of chronic obstructive pulmonary disease (COPD). COPD is a common lung disease and accounts for a large number of hospital admissions each year in England. COPD is frequently complicated by episodes of acute worsening of respiratory symptoms, termed 'exacerbations. Severe exacerbations of COPD may lead to respiratory failure, non-invasive ventilation (NIV) is a method of supporting the patients' normal breathing efforts, using a mask fitted to their face connected to a ventilator, and can be lifesaving during exacerbations of COPD complicated by respiratory failure.<br><br>NHS Digital advised IGARD that the version of the protocol that had been shared with IGARD, v2.3, had since been updated and there was now a v2.4.<br><br>**Discussion:** IGARD welcomed the application and noted the importance of the study.<br><br>IGARD noted the update from NHS Digital in relation to the updated protocol and asked that the updated paragraphs from v2.4 were shared with IGARD and that the revised protocol v2.4 was saved on NHS Digital's Customer Relationship Management (CRM) system. |

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| | IGARD queried the nature of the funders' business, which was to produce ventilator type products, and asked that section 5(e) (Is the Purpose of this Application in Anyway Commercial) was updated to clarify this and to confirm if there may be the potential of possible indirect benefits accruing to the funder(s). Separate to this application, IGARD noted that when NHS Digital consider their Commercial Standard that they should consider whether any potential benefits are flowing to other parties involved, including funders and which not be apparently financial.<br><br>IGARD noted that the applicant's privacy notice was significantly non-compliant and in particular the applicant's study website which required significant updates. NHS Digital noted that the poster was no longer displayed and had fed back to the applicant their own concerns with regard to the applicant's Privacy Notice. IGARD asked that the website was updated to ensure it was compliant with the General Data Protection Regulation (GDPR) notice requirements; that it had a clear and accurate description of the data flow process; that it was clear that no *"anonymised"* data would be flowing to NHS Digital and that a full and transparent description of all aspects of the study, including (but not limited to) the involvement of the commercial funders.<br><br>IGARD noted that the study outlined had moral and ethical issues, however the application did not make reference to these, and asked that section 5 (Purpose / Methods / Outputs) was updated to make clear that the moral and ethical issues relating to the production of the tool (given the proposed output of predicting future risk of death) have been considered by the applicant, including (but not limited to) involvement of the Patient and Public Involvement (PPI) Committee.<br><br>IGARD queried the information provided in section 5(d) (Benefits) (ii) (Expected Measurable Benefits to Health and/or Social Care) and suggested a number of amendments, including (but not limited to) amending the word *"data"* to *"output";* by amending the word *"will" to "may"*; reviewing the timeframe stated in the current climate and removing reference to *"researchers".*<br><br>IGARD noted the reference to *"anonymised data"* in section 5(a) (Objective for Processing) and asked that this removed and replaced with *"aggregated numbers with small numbers suppressed"* to be consistent with the rest of the application.<br><br>IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices.<br><br>**Outcome Summary:** recommendation to approve subject to the following condition:<br><br>1. The applicant to update the study website to ensure:<br>a) That it is compliant with the GDPR notice requirements.<br>b) There is a clear and accurate description of the data flow process.<br>c) It is clear that no "anonymised" data will be flowing to NHS Digital.<br>d) There is a full and transparent description of all aspects of the study, including (but not limited to) the involvement of the commercial funders.<br><br>The following amendments were requested:<br><br>1. To provide IGARD with a copy of the updated paragraphs in the updated protocol (v2.4) and ensure the revised protocol is saved on CRM.<br>2. To update section 5(e) to make clear the nature of the funders' business and there may be the potential of possible indirect benefits accruing to the funders.<br>3. To make clear within section 5 that the moral and ethical issues relating to the production of the tool have been considered by the applicant, including (but not limited to) involvement of the PPI Committee.<br>4. To review section 5(d) (ii) to: |

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| | a) amend the word *"data"* to *"output"*.<br>b) amend the word *"will"* to *"may".*<br>c) reviewing the timeframe stated in the current climate.<br>d) remove reference to *"researchers"*.<br>5. To remove the reference to *"anonymised data"* in section 5(a) and replace with *"aggregated numbers with small numbers suppressed"* as referenced elsewhere in the application.<br><br>It was agreed the condition would be approved Out of Committee (OOC) by IGARD members. |
| **2.5** | <u>University of East Anglia: ARRISA-UK study request for secondary care data for asthma patients at participating GP practices in England and Wales (Presenter: Stuart Blake) NIC-79526-V8F2X</u><br><br>**Application:** This was a new application for Hospital Episodes Statistics (HES and Civil Registrations data for the purpose of a study to determine whether flagging the electronic health records of people identified as being at risk of asthma attacks and training staff on the action to take when seeing the flag reduces asthma related crisis events over a 12 month period. The study will also find out how many people have well controlled asthma, what medications are prescribed for asthma, how often patients attend appointments and if they stop smoking. The study will calculate how much this costs and whether it improves (or interferes with) the care of other patients with asthma in the practice.<br><br>**Discussion:** IGARD welcomed the application and noted the importance of the study. NHS Digital noted that the application had not been updated since the Covid-19 pandemic.<br><br>IGARD noted that the University of East Anglia was listed as the sole Data Controller within the application but that the evidence presented as part of supporting documentation was that others could also be considered Data Controllers. IGARD noted that the University of East Anglia may indeed be the sole Data Controller and that the study had been running for many years. However in light of the information provided in the collaboration agreement provided, for example in point 2.2 which noted the study would be carried out under the direction of the Co-Investigators, further clarity was needed since there were references to co-investigators, a trial management group and a trial steering committee and it was not clear from the information provided who was making the decisions and determining the purpose and means of the study and use of the data.<br><br>IGARD queried the reference in section 5(a) (Objective for Processing) to *"institutional consent"* and asked that further clarity was provided on this; or asked that if this reference was not relevant that it was removed.<br><br>IGARD noted the helpful Patient and Public Involvement (PPI) outlined in the Health Research Authority Confidentiality Advisory Group (HRA CAG) supporting materials and asked that this was also replicated in section 5 (Purpose / Methods / Outputs) of the application, for example the reference to social media dissemination.<br><br>IGARD noted the information outlined in supporting document 3.1, the study protocol (point 7.1.1) that provided an explanation outlining how the *"at risk"* members of the cohort were determined, and asked that this was replicated in section 5.<br><br>IGARD queried the information provided in section 5(d) (Benefits) in relation to the projected savings and asked that consideration was given to using terms such *"transactional costs"* and *"reflected in alternative provision"*.<br><br>IGARD noted the outcomes outlined in section 5(d) (ii) (Expected Measurable Benefits to Health and/or Social Care) and asked that applicant ensured that the language used reflected |

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| | realistic outcomes given the nature of the study and the data that was being requested, for example by replacing *"will"* with *"may"*.<br><br>IGARD noted that the territory of use in section 2(c) (Territory of Use) was listed as *"England / Wales / UK"* and asked that this was updated to ensure the correct information was reflected.<br><br>IGARD queried the Data Protection Act (DPA) Registration dates in section 1(b) (Data Controller(s)) and section 1(c) (Data Processor(s)) and noted they were due to expire (03/04/2020) and asked that these were updated to reflect the correct dates.<br><br>IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices.<br><br>**Outcome Summary:** recommendation to approve subject to the following condition:<br><br>1. To clarify why the University of East Anglia is considered the sole Data Controller, in light of the information provided in the collaboration agreement (for example point 2.2) noting that that study will also be carried out under the direction of the Co-Investigators.<br><br>The following amendments were requested:<br><br>1. To provide further clarity on the reference to *"institutional consent"* in section 5(a); or to remove reference if not relevant.<br><br>2. To replicate the helpful PPI information outlined in the HRA CAG supporting materials in section 5, for example reference to social media dissemination.<br>3. To replicate the explanation outlined in SD3.1 (point 7.1.1) within section 5 outlining how the *"at risk"* members of the cohort are determined.<br>4. To review section 5(d) to ensure that when referring to the projected savings, consideration is given to using terms such "transactional costs" and "reflected in alternative provision".<br>5. To ensure the language in section 5(d) (ii) reflects realistic outcomes given the nature of the study and the data being requested, for example replacing "will" with "may".<br>6. To update section 2(c) to ensure the correct territory of use is reflected.<br><br>7. To update section 1(b) and 1(c) to ensure this reflects the correct DPA Registration expiry dates.<br><br>It was agreed the condition would be approved Out of Committee (OOC) by IGARD members. |
| **2.6** | <u>eRS Class Action Application: An amendment for CCGs to receive NHS e-Referral Service (e-RS) data set (Presenter: Bethan Thomas) NIC-372946-V5T8D</u><br><br>**Application:** This was a new Class Action amendment for CCGs to receive NHS e-Referral Service (e-RS) dataset. The NHS e-Referral Service (e-RS) is a national IT system that enables patient referrals, primarily from GPs to first hospital or clinic appointments, to be booked into health care services at a location, date and time to suit the patient. The primary purpose of processing e-RS data is to enable the correct operation of the e-RS system. Subsequent processing transforms the data into appropriate extracts for recipients.<br><br>**Discussion:** IGARD queried if the 'referral letter capture' outlined in the application included free text and asked that confirmation was provided in the application confirming that it did not include any free text.<br><br>IGARD noted that the application was not always easy to understand and suggested that it be reviewed throughout to ensure that it was written in language suitable for a lay reader and that it was amended where necessary. In addition, to ensure that any further application(s) to IGARD were presented on the correct (most recent) application summary document. |

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| | IGARD noted the stated outputs and goals in the application and asked that these were reviewed to ensure they reflected realistic expectations given the nature of the data flowing the nature of the recipients of the data.<br><br>IGARD queried the statement in the 'summary section' of the application that stated *"patients being directed to community-based alternatives"* and asked that confirmation was provided if this was "pathways to the community"; and if so to amend as appropriate.<br><br>IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, since this was the first application of this type of data and that future applications should be presented to IGARD for the short term.<br><br>IGARD offered the support of its specialist GP members for progressing this application and helping to set a precedent for future applications of this type.<br><br>**Outcome Summary:** recommendation to approve<br><br>The following amendments were requested:<br><br>1. To provide confirmation within the application that the (referral) letter capture does not include any free text.<br>2. To review the application throughout to ensure it is written in a language suitable for a lay reader and to amend where necessary.<br>3. To ensure that the stated outputs and goals reflect realistic expectations given the nature of the data flowing and the nature of the recipients of the data.<br>4. To review the statement in the 'summary' section *"patients being directed to community-based alternatives"* and confirm if this *"pathways to the community";* and to amend as appropriate.<br><br>The following advice was given:<br><br>1. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, since this was the first application of this type of data.<br>2. To ensure that any further application to IGARD is presented on the correct (most recent) application summary document. |
| **3** | <u>Covid-19 update</u><br><br>IGARD noted that there were no Covd-19 related items to discuss at this week's meeting. |
| **4** | <u>Returning Applications</u><br><br>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.<br><br>• NIC-204559-J4H7T NHS England<br>• NIC-204565-L5J5F University College London Hospitals NHS Foundation Trust<br>• NIC-81519-G1T5F University of Birmingham<br>• NIC-147947-CGW0Y The Dudley Group NHS Foundation Trust<br><br>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 which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis. |

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| **5** | AOB: |
| **5.1** | HQIP applications with NHS England as a joint Data Controller<br><br>NHS Digital and IGARD discussed the proposed process for HQIP audit applications where there is one amendment to add NHS England as a Data Processor. It was agreed that for transparency of process that these applications would be noted under AOB which would include the NIC number and applicant name and purpose of amendment. |
| **5.2** | IGARD Terms of Reference<br><br>The IGARD Terms of Reference were discussed and although these are due to be reviewed / updated over the coming year as part of wider work, it was agreed by members that given the current situation with Covid-19 and the pressures already upon NHS Digital and IGARD, this would be delayed and reviewed again over the coming months to agree a suitable way forward. |
| **5.3** | NHS Digital Commercial Standard<br><br>IGARD agreed to review the current Commercial Standard again, following a re-review and forward comments to NHS Digital for comment, finalisation and sign off, as per process. |
| **5.4** | NHS Digital Cloud Storage Standard<br><br>The IGARD Chair along with GP specialist members agree to re-review the Cloud Storage Standard and forward comments to NHS Digital for comment, finalisation and sign off, as per process. |
| **5.5** | IGARD Meeting Quoracy<br><br>In light of the ongoing situation with Covid-19, and following consideration by IGARD members, it has been agreed with NHS Digital that from the 26th March 2020 meeting, the in-meeting quoracy may be temporarily reduced to three members (from four members), which must include a Chair and at least two specialist members. This is to ensure business continuity in the event that Covid-19 impacts on members ability to dial-in to meetings (due to illness or caring for a household member) and to support those IGARD members who have other roles linked to the Covid-19 response. This will be reviewed as and when required, but no less than monthly, and in response to new guidance that is released. This relates to Covid-19 only.<br><br>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. |

## Independent Group Advising on Releases of Data (IGARD): Out of committee report 27/03/20

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-21083-B6C5J | University of Surrey | 12/03/2020 | 1. To amend the application throughout to ensure there is no reference to 'research' in order to ensure the application reflects the parameters laid out by Regulation 3, Health Service (Control of Patient Information) Regulations 2002, in that research cannot be undertaken with data supplied in reliance on that Regulation. | IGARD Chair | OOC by 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 notified to IGARD