Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 10 October 2019

In attendance (IGARD Members): Sarah Baalham, Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Eve Sariyiannidou, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Garry Coleman, Dave Cronin, Louise Dunn, James Humphries-Hart, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Anomika Bedi, Geoffrey Schrecker.

1	**Declaration of interests:** Nicola Fear noted professional links to the National Institute for Health Research (NIHR) Bioresource [NIC-205004-D2F8N] but noted no specific connections with the application of staff involved and it was agreed that this was not a conflict of interest **Review of previous minutes and actions:** The outcomes of the 3rd October 2019 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting. The minutes of the 3rd October 2019 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	Imperial College London: TOGETHER Study (Presenter: Louise Dunn) NIC-157873-F6F8K **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for a study (Imperial and The LOndon GEneral Practice-based InvesTigation of Cardiovascular HEalth and Risk Factors (TOGETHER) among diverse populations) aiming to understand the burden of cardiovascular risk factors across different ethnic groups. The direct and indirect burden of cardiovascular disease (CVD) on the NHS and UK economy is estimated to be around £9 and £19 billion each year respectively. With the presence of racially diverse communities, prevention tools and strategies derived from population studies need to consider these groups to ensure services provided by the NHS are more appropriate to the population they serve. The application was been previously considered on the 12th September when IGARD had deferred pending: to provide clarity throughout the application if the cohort age group are those aged 40-74 (as part of the NHS Health Check) or those aged 30-90; and to provide a further explanation within section 3(b) of how the cohort numbers were agreed; following clarification of the cohort age group, to ensure that ethics approval and other relevant support is still applicable; throughout the application to amend the reference from “consent form” to “participation agreement” (or similar); to update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience (for example when referring to “burden”); to remove the relevant paragraphs referencing ‘processing’ from section 5(c) and include within section 5(b); to remove the reference to ‘funding’ from section 5(b); to update section 1 and section 5(b) to clarify that the data is requested for a specific point in time and that should the applicant request further HES data that this will be subject to an amendment application to NHS Digital (and the necessary approvals being provided); to

	update section 5(c) and section 5(d) to ensure the information provided relates to the processing outlined and the data received in this specific application; to clarify that all stated benefits can be realised from the type of data requested in this application; to amend the application to state that the funder will have no scientific input into this study and no influence over the outputs; and to also include this as a special condition in section 6; the applicant to provide to NHS Digital patient-focussed transparency material, for example a leaflet and poster (noting that draft transparency materials have been provided for the Practice Managers but not focussed on the patient cohort). **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD noted that the previous deferral point (1) requesting further clarity on the cohort age group had been addressed and that the study was looking at those aged 30-90, and agreed that justification had been made for the wider age range, however IGARD noted that there were still references within the application and supporting documents to “health checks” and asked that these were removed and that there were no contradictory or conflicting statements in the application in relation to this amendment. IGARD queried the inconsistencies in the cohort numbers referenced in the application, supporting document 7.2, the Integrated Research application System (IRAS) form and supporting document 7.3, the ethics approval notification and asked that a further explanation was provided outlining the reason (if any) for this inconsistency in cohort numbers. IGARD noted that that section 5(d) (Benefits) had been updated with additional information addressing the previous deferral point (9) querying if the benefits could be realised from the type of data that was being requested, however advised that further clarity was required with a clearer explanation of how the benefits derived from **this** study could be used. IGARD also suggested that the emphasis on any benefits derived from **future** data flows should be reduced to ensure there was a clear distinction between current and future benefits. IGARD queried the reference in the application that specific patient groups were being targeted and asked for further clarification if the stated outputs could still achieve the overall aim of the project. NHS Digital advised that the applicant had not yet provided any of the revised transparency material requested as part of a previous deferral point (11). IGARD asked that NHS Digital provide written confirmation that they had satisfied themselves that the content of the materials for patients had met NHS Digital’s fair processing criteria and that there was a suitable plan in place for disseminating this, for example via a poster / pamphlet / TV screen in GP waiting rooms. IGARD also suggested that the applicant may also wish to consider involving GP patient groups. IGARD suggested the applicant may wish to consider whether the agreements with the GP practices fully explained the wide range of the cohort (i.e. that it is not a more limited “health check” cohort). **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide an explanation of the inconsistencies of the cohort numbers referenced in the application, ethics approval and the IRAS form. 2. To clarify that all stated benefits can be realised from the type of data requested and processing outlined in this application and to clearly explain how they will use the benefits derived from this study; and to amend the application to reduce the emphasis on the benefits that may be derived from any future data flows.

	3. NHS Digital to provide confirmation that they have satisfied themselves that the content of the revised transparency materials for patients meet NHS Digital's criteria and that there is a suitable plan in place for their dissemination (for example via a poster/pamphlet / TV screen in GP waiting rooms and to also consider involving GP patient groups etc). The following amendments were requested: 1. To amend the application throughout and the relevant supporting documents to remove all references to "health checks" and to ensure there no contradictory or conflicting statements in the application. 2. To provide clarification that by targeting the patient groups outlined in the application, the stated outputs can still be achieved. The following advice was given: 1. IGARD suggested the applicant may wish to consider whether the agreements with the GP practices fully explain the wide range of the cohort (i.e. that it is not a more limited "health check" cohort). It was agreed the condition be approved Out of Committee (OOC) by IGARD Members.
2.2	<u>National Institute for Health Research (NIHR) Bioresource: Access to NHS PDS Spine Mini Service for participant-facing research infrastructure project (Presenter: Stuart Blake) NIC-205004-D2F8N</u> **Application:** This was a new application for access to identifiable data on the NHS Personal Demographic Service Spine lookup service. The NIHR Bioresource maintains a large database of potential research participants (currently around 100,000) who can be invited to participate in a range of medical studies. Individuals give their consent for the NIHR BioResource to hold their details and to contact them about studies that they would be eligible to participate in. Prior to contacting individuals about any particular research study, NIHR BioResource staff carry out a check of the participant's details to reduce the risk of attempting to contact any individual who is now deceased, at present this check is carried out by a research nurse using the NHS Spine system within the hospital, but manually checking each individual's details one by one is a time consuming and inefficient process. This request is for the NIHR BioResource staff to instead be granted continuous access to the Personal Demographics Service (PDS) system in order to check participant details more efficiently. **Discussion:** IGARD supported the objective of the application in reducing any distress to the families of the deceased research participants that form part of the NIHR Bioresource database. IGARD noted the reference in the addresses noted in section 2 (Locations) to ***"****AIMES Virtual Private Cloud"* and asked that confirmation was provided that AIMES Management Services was not providing Cloud storage and asked that section 5(b) (Processing Activities) was updated to reflect this or, if AIMES Management Services were providing cloud storage that the relevant standard wording was inserted. IGARD noted the information provided in supporting document 3, the protocol that stated *"The NIHR BioResource has undergone an extensive restructure, and since Dec 2017 comprises of 13 local centres with Cambridge as the headquarters."*, which was also reflected in section 1 (Abstract) of the application. IGARD and asked that section 5(b) was updated confirming that only the Bioresource Headquarters at the Cambridge University Hospitals NHS Foundation Trust would access the data and not the other Bioresource local centres and that this was also replicated as a special condition in section 6 (Special Conditions).

	IGARD noted the statement provided in section 1 that stated *"NHS Digital data obtained under this agreement will not be shared with the third party organisations running these research studies."* should be replicated in section 5(b) and as a special condition in section (6). IGARD queried the statement in section 1(c) (Data Processor(s)) in relation to InHealthcare that stated *"This has been referred to the DARS security consultant for review"* and asked that this was updated to confirm whether NHS Digital's security had completed the review of InHealthcare and to note any issues that were raised. IGARD queried the statement in section 1 (Abstract) that stated *"This request is for the NIHR BioResource staff to instead be granted continuous access…"* and asked that section 5(a) (Objective for Processing) was updated to include a statement that the applicant would only use the data provided and only to achieve the outcomes outlined in this application. IGARD noted the statement in section 1 that stated *"In some instances, staff working within the NIHR BioResource may be substantively employed by the University of Cambridge…"* and asked that for transparency this was also replicated in section 5 (Purpose / Methods / Outputs). IGARD noted the sentence in section 5(b) *"The BioResource will also use the service to identify participants who have joined the study more than once – a risk with any long-running nationwide recruitment campaign – and may also subsequently use GP details…"* and asked that this was amended to remove *"…and may also subsequently use GP details…"* as it was not relevant. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To provide confirmation that AIMES Management Services is not providing Cloud storage (and if they are to insert the relevant standard wording) and to update section 5(b) to reflect this. 2. To update section 5(b) and to include a special condition in section 6 confirming that only the Bioresource Headquarters at the Cambridge University Hospitals NHS Foundation Trust will access the data and not the other Bioresource local centres referenced in the protocol. 3. To update section 5(b) and to include a special condition in section 6 stating that the NHS Digital data obtained under this Data Sharing Agreement will not be shared with the third party organisations running these research studies. 4. To update section 1(c) to confirm whether NHS Digital's security has completed the review of InHealthcare and to note any issues raised. 5. To update section 5(a) to include a statement that the applicant will only use the data provided and only to achieve the outcomes outlined in this application. 6. To amend section 5(b) (3rd paragraph) to remove the end of the sentence that starts *"and may also subsequently use GP details…".* 7. To update section 5 to replicate the information in section 1 that starts *"In some instances, staff working within the NIHR BioResource may be substantively employed by the University of Cambridge…"*
2.3	<u>University of Bristol: Evaluation of alcohol health champions programme in Greater Manchester (Presenter: Dave Cronin) NIC-268750-B3T4W</u> **Application:** This was a new application for aggregated Hospital Episode Statistics (HES) Accident and Emergency data for the purpose of evaluating a study of the effectiveness of the Communities in Charge of Alcohol (CICA) programme. The programme is part of a newly devolved Greater Manchester Combined authority's alcohol strategy to reduce alcohol misuse

	through training lay volunteers to become alcohol health champions (AHCs). AHCs will facilitate communities to tackle alcohol-related harm by influencing alcohol availability through local licensing processes. NHS Digital advised IGARD that the applicant had advised that they did not consider the data to be 'personal data' and that NHS Digital had also looked into the linkages and agreed that it did not appear to be personal data. **Discussion:** IGARD noted the update from NHS Digital's that the data requested did not appear to be personal data and following a discussion amongst members on the data that was being requested and the linkage outlined, IGARD agreed with NHS Digital's analyses that the data was not personal data. IGARD suggested that the sentence in section 5(a) (Objective for Processing) that stated: *"…there are no moral or ethical issues raised..."* was removed since it was not necessary to include in the application. IGARD asked that for clarity, section 5 (Purpose / Methods / Outputs) of the application was updated to state that the funder would not have influence on the outcomes nor suppress any of the findings of the research / study. IGARD noted the references in the application to other "work packages" and asked that a special condition was added to section 6 (Special Conditions) explicitly stating that the data received under this Data Sharing Agreement (DSA) would not be accessed by the organisations that work under the other work packages and that the data received under this DSA would not be linked to data received under the other work packages. IGARD suggested that the applicant may wish to consider (if they haven't already) the level of Patient and Public Involvement (PPI) currently, and in the future, which may take the form of membership of steering groups or other such initiatives to involve the community. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To remove from section 5(a) reference to '*there are no moral or ethical issues*". 2. To confirm within section 5 that the funder will not have influence on the outcomes nor suppress any of the findings of the research. 3. To update section 6 to include a special condition to explicitly state that the data received under this Data Sharing Agreement will not be accessed by the organisations which work under the other work packages referenced, and that the data received under this Data Sharing Agreement will not be linked to data received under the other work packages. The following advice was given: 1. IGARD suggested that the applicant may wish to consider (if they haven't already) the level of PPI currently, and in the future, which may take the form of membership of steering groups or other such initiatives to involve the community.
2.4	<u>University of Oxford: The role of patient factors, surgical factors and hospital factors upon patient outcomes and NHS costs in the treatment of upper limb musculoskeletal injuries and infections: spatial and longitudinal analysis of routine data (Presenter: Dave Cronin) NIC-295342-W3Z6L</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care, HES: Civil Registration (Deaths) bridge and Civil Registration (Deaths) Secondary Care Cut. The purpose is to investigate the trends in surgery undertaken for the

	treatment of upper limb injuries and infections, and the complications that follow surgery. By understanding the burden of surgery needed to treat upper limb injuries and infections on the National Health Service (NHS) and observing temporal and geographic trends, services can be better planned. In addition, understanding injury patterns and risk factors for infections allows targeted preventative strategies to be considered. Lastly, analysis of upper limb injury and infection burden allows clinical research to be directed towards better understanding and managing the most prevalent and impactful conditions. **Discussion:** IGARD noted and commended the Patient and Public Involvement (PPI) efforts with this study as outlined in the application. IGARD had a lengthy discussion on the amount of data being requested (22 years) and were advised by NHS Digital that the applicant was unable to minimise the data any further. IGARD asked for further clarification as to whether there was any further data filtering or data production steps that NHS Digital could undertake before the data reached the applicant to address the data size set, and to ensure all possible data minimisation had taken place in accordance with Article 5(1)(c) of the General Data Protection Regulation (GDPR). If those steps could not be taken by NHS Digital then a further explanation should be provided in conjunction with NHS Digital's Data Minimisation Standard (paragraphs 1, 3, 4, 5, 6, 11 and 12). IGARD noted that both the data production specification and the application referred to the inclusion of both adults **and children's** data, however supporting document 1.0, the protocol only referred to adult data and asked that a further explanation was provided on the inconsistencies in respect of the reference / request for children's data. IGARD also asked that if children's data was included, that further written justification was provided as stipulated in the introductory paragraph of NHS Digital's Data Minimisation Standard. IGARD asked that if the cohort did not include children under the age of 16, that the data minimisation column in section 3(b) (Additional Data Access Requested) and the production specification was updated to make it clear that they would not be included in the data set. IGARD noted from the supporting documents that the research outlined would support the fulfilment of two 'Doctor of Philosophy' (DPhils) and asked that further information was provided of how the significant size of the cohort would be processed and to also clarify if the data provided was proportionate to the academic endeavour and whether there were sufficient resources available to ensure the project was carried out to completion, since this assurance was not apparent within the materials presented. IGARD also queried the link between the volume of data required and how it was necessary to meet the research aims stated in section 5 (Purpose / Methods / Outputs) and asked that a further written explanation was provided. IGARD noted that within section 5, it was not always clear that this was a 'retrospective study' and asked that where appropriate updates were made to accurately reflect this. IGARD also noted that some of the acronyms within the application were not always defined upon first use and suggested the application be amended as necessary to make this clear. **Outcome Summary:** Unable to recommend for approval 1. To provide clarification if there is any further data filtering or data production steps that NHS Digital could undertake before the data reaches the applicant to address the data set size and ensure all possible data minimisation has taken place in accordance with Art 5(1)(c) GDPR (and if not, an explanation of why those steps cannot be taken by NHS Digital; paragraphs 1, 3, 4, 5, 6, 11 and 12, NHS Digital's Data Minimisation Standard refers).

	2. To provide an explanation on the inconsistencies between the application and the protocol in respect of the reference / request for children's data and if children's data is included, to specifically justify the need for child data (as stipulated in the introductory paragraph of NHS Digital's Data Minimisation Standard). 3. If the cohort does *not* include children under 16, to update the data minimisation column in section 3(b) and production specification to make clear that they are not included in the data set. 4. Since this research supports fulfilment of two DPhils, to provide further information on how the significant size of the cohort outlined will be processed and to clarify if the data provided is proportionate to the academic endeavour and whether there are sufficient resources available to ensure the project is carried out to completion. 5. To explain the link between the volume of data required and how it is necessary to meet the research aims stated in section 5. 6. To amend section 5 to make it clear that this is a retrospective study. 7. IGARD suggested that all acronyms upon first used in the application be defined and further explained, as may be necessary for a lay reader.
2.5	<u>NHS Crawley CCG: DSfC - NHS Crawley CCG; RS & IV (Presenter: James Humphries-Hart) NIC-91838-H0B9N</u> **Application:** This was an renewal application for identifiable Secondary Uses Service (SUS+) data; and an amendment application for identifiable Mental Health Services Data Set (MHSDS) for the purpose of Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do, 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. NHS Digital advised that this application had been amended prior to submission to reflect IGARD's comments received on a similar application on the 3rd October 2019. **Discussion:** IGARD noted the update from NHS Digital on the updates made to this application following a discussion on a similar application on the 3rd October 2019 and had no further comments to make. **Outcome Summary:** recommendation to approve
3 **3.1**	**AOB:** **Carnall Farrar - NIC-243790-Y8K8C** NHS Digital's Associate Director, Data Access advised that following IGARD's recommendation to approve the Carnall Farrar (NIC-243790-Y8K8C) application on the 26th September 2019, that a further discussion would need to take place at a future IGARD meeting to review in-line with NHS Digital's Standards. **ACTION:** IGARD Secretariat to include Carnall Farrar discussion on the agenda for the 31st October 2019 IGARD meeting.
3.2	**Dr Foster Limited - NIC-68697-R6F1T** IGARD discussed the conditions set for this application, that were agreed at the meeting on the 29th August 2019. Following ratification of the conditions at the meeting on the 12th September 2019, further discussions have taken place between IGARD and NHS Digital and

	the IGARD Chair has taken Chair's action to set aside the conditions originally listed, however the amendments remain the same. The Chair has highlighted that there are important issues arising from the original conditions set that will be taken forward with the Office of the Data Protection Office (DPO). **ACTION:** IGARD Chair to contact the Chief Information Assurance Officer in the Office of the DPO to discuss the issue of Date of Death data.
3.3	**NIC-366913-C2V5F** NHS Digital advised IGARD that this application that was previously discussed at the IGARD meeting on the 12th July 2019 had been presented on behalf of the National Institute for Health Research (NIHR) Bioresource, however subsequent investigations by NHS Digital have revealed that an error had occurred and it should have been presented for the NIHR Clinical Resource Network Centre.
3.4	**Legal basis 261(7)** NHS Digital discussed with IGARD that where there is an application to disseminate identifiable data with s251 support, the data held/requested tables state the lawful basis for dissemination as either i) Health and Social Care Act 2012 – s261(7) and National Health Service Act 2006 – s251 – 'Control of patient information', OR 2) Health and Social Care Act 2012 – s261(7). The IGARD Chair advised that there was not a different approach across organisations, a different part of the Act must be referenced.
3.5	**Medical Research Information Service (MRIS) and Data Minimisation** As part of IGARD's continuous learning and development, NHS Digital presented updates on Medical Research Information Service (MRIS) and Data Minimisation. IGARD welcomed the presentations and thanked NHS Digital for the time and effort taken in doing this.
3.6	IGARD had received notification that Priscilla McGuire had formally resigned from her Lay member role with immediate effect and wished to extend their sincere thanks for her contribution over the last 9 months during her tenure on IGARD. There was no further business raised, the IGARD Deputy 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 04/10/19

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

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-147847-P6MMR	King's College London	26/06/2019	1. To provide an explanation within section 5(a) as to the source of data for the two control groups outlined in the application and to confirm that no data will be disseminated from NHS Digital for these cohorts. 2. To explicitly state within section 5 the numbers of cancers and deaths required to achieve the statistical power threshold of 80% for the study.	Deputy Chair	OOC by Deputy Chair	"Should the agreement come back for renewal, or any further application related to the groups involved in this study be received, then these should come to IGARD for review"
NIC-204376-Y0V5Y -	Manchester University NHS Foundation Trust	19/09/2019	1. To update section 5(a) to clarify what the 'Exit Strategy' relates to, what the applicant means by 'anonymisation' and how the Exit Strategy complies with the CAG advice to uplift the consent materials and process.	IGARD members	OOC by IGARD members	

In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None