Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 27 June 2019

In attendance (IGARD Members): Maria Clark, Nicola Fear, Priscilla McGuire, Eve Sariyiannidou, Geoffrey Schrecker (Deputy Chair).

In attendance (NHS Digital): Stuart Blake, Dave Cronin, Frances Hancox, James Humphries-Hart**,** Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Kirsty Irvine (Chair), Maurice Smith.

1	**Declaration of interests:** Nicola Fear noted a professional link to NIC-147847-P6MMR King's College London and since she was the applicant for this application would not be part of the discussion. It was agreed Nicola would not remain in the meeting for the discussion of that application. Eve Sariyiannidou noted professional links to HQIP [NIC-237669-T9W5N University of Nottingham] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest Maria Clark, Priscilla McGuire, Eve Sariyiannidou and Geoffrey Schrecker noted a professional link to the applicant at King's College London [NIC-147847-P6MMR] but noted no specific connection with the application and it was agreed that this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 20th June 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data applications**
2.1	<u>University College London: Policy Research Unit for Children, Young People and Families (Presenter: James Humphries-Hart) NIC-393510-D6H1D</u> **Application:** This was an amendment and renewal application for pseudonymised Hospital Episode Statistics (HES), Civil Registrations and Emergency Care Data Set (ECDS) for a programme of research to determine variation in use of secondary care services by children and young people over time and their transition to adult services; to determine risk factors for emergency use of secondary care and risk factors for recurrent use; and to conduct prognostic analyses for children and young people based on diagnosis and procedure codes to identify risk factors for emergency hospital care and for subsequent long-term adverse outcomes into adulthood. NHS Digital noted that the application should be updated to reflect recent discussions with regard data disseminated under this application only being used for different purposes after they have been approved by NHS Digital. NHS Digital also noted that the data processor address for UCL had been updated to correctly reference the address. NHS Digital noted that additional wording had been included within the application that the re-identification of data was not permitted under this application.

	Discussion: IGARD noted and supported the amendments made to correctly reference the UCL's address in section 2(a) (Processing Locations) and that reidentification of data was not permitted under this application. IGARD noted that since data disseminated under this agreement would be linked to other audits, that a clear narrative was inserted in section 5 (Purpose / Methods / Outputs) explaining that data disseminated under this application can only be used for different purposes after those different purposes have been approved by NHS Digital under separate applications and a live Data Sharing Agreement (DSA) was in place. In addition a special condition should be included in section 6 (Special Conditions) stating the same. IGARD noted that supporting document 1.2, Department of Health supporting document 2018, included reference to linked records and unlinked mortality data and were unclear how this aligned, and suggested that further clarification be included in section 3(a) (Data Access Already Given) and section 3(b) (Additional Data Access Requested) outlining how the data aligned to this letter. Additionally, IGARD asked for confirmation of what was meant by the term "*hospital administrative data*" and that it covered the data being released under this application, aligning with section 3(b). IGARD noted that supporting document 1.2 referenced England and Scotland and queried if the data requested included Scottish residents and sought clarification if the data disseminated included any Scottish data in general or if the data disseminated only related to English residents who were registered with a Scottish General Practitioner (GP), now or in the past. IGARD queried the data sets requested and that confirmation be sought that the applicant required the whole HES dataset and that narrative be included in section 3(b). IGARD noted that Civil Registrations data was the new name for ONS Mortality data and had moved to NHS Digital controllership and suggested that section 1 (Abstract) be updated to reflect this recent change and why patient objections did not apply. IGARD queried if any data flowed into NHS Digital for this particular application and NHS Digital confirmed this was not the case. It was suggested that section 5 (Purpose, Methods, Outputs) be updated to confirm that no data flowed into NHS Digital as part of this application. IGARD noted reference to a number of technical phrases and words, including "parity", "international self-injury" and "adversity related" within section 5 and suggested that it be updated to ensure the use of technical jargon was used only where necessary and that it was written in a language suitable for a lay reader. IGARD suggested that the purpose of the application, as outlined in section 5, was more clearly defined in section 1 (Abstract). **Outcome Summary:** recommendation to approve subject to the following conditions 1. To insert in section 5 a clear narrative explaining that data disseminated under this application can only be used for different purposes after those different purposes have been approved by NHS Digital under separate applications and a live DSA is in place. 2. To include a Special Condition in section 6 that data disseminated under this application can only be used for different purposes after those different purposes have been approved by NHS Digital under separate applications and a live DSA is in place. 3. To confirm what the Department of Health mean with regard to "hospital administrative data" and to ensure it covers data being released under this application, aligning it with section 3(b) 4. To provide confirmation within section 3(b) whether the applicant needs the whole of the HES dataset.

	5. To provide clarification in sections 3(a) and 3(b) how the linked records and unlinked mortality data aligns with Department of Health letter. 6. Confirmation in section 5 if the data disseminated includes any Scottish data in general or if the data disseminated relates only to English residents who are registered with Scottish GP now or in past. The following amendments were requested: 1. To update the abstract to clarify the recent changes to ONS data and why patient objections do not apply. 2. To confirm in section 5 that there are no data flows into NHS Digital as part of application. 3. To update section 5 to ensure it is written in a language suitable for a lay reader and to explain terminology such as "adversity related", "international self-injury" and "parity". 4. To update the abstract to clearly explain the purpose(s) of this application. It was agreed the conditions would be approved OOC by IGARD Members
2.2	<u>University of Nottingham: Cerebrovascular accident and Acute coronary syndrome and Perioperative Outcomes study (CAPO) (Presenter: Stuart Blake) NIC-237669-T9W5N</u> **Application:** This was a new application for pseudonymised Civil Registrations and Hospital Episode Statistics (HES) data for a study aiming to assess the impact of clinically recognised pre-operative stroke (cerebrovascular accident; CVA) and acute coronary syndrome (ACS) on perioperative outcome; if the characteristics and management of stroke and ACS modify perioperative outcome; and how are the effects of stroke and ACS modified by surgical procedure. The expected outcomes are robust estimates of time-dependant risks associated with stroke and ACS, stratified by surgical type and characteristics of stroke and ACS. The application was been previously considered on the 9th May 2019 when IGARD had deferred pending: to provide clarification in section 5 why the University of College London and the University of Wisconsin School of Medicine are not considered as Data Controllers as all co-investigators seem to be equally involved in the design and the performance of the project as described in the protocol; To update section 1 to make clear that HQIP is the Data Controller for the audit data; to clarify within section 5 any involvement of Nottingham University Hospitals NHS Trust; to provide the appropriate legal basis for the flow of NICOR and SSNAP data into NHS Digital; to update section 5(a) and 5(d) to carry out a careful review of the numbers and percentages quoted to ensure accuracy and that it clearly reflects the research to be undertaken; to update section 5 to ensure the use of technical jargon is used only where necessary; and where it is necessary, to be also written in language suitable for a lay reader; in order to meet the necessity test, to justify the quantum of the data requested and to provide an explanation as to why such a large amount of data is required (e.g. sufficient statistical power or for the effective research into sub-groups) and to clarify what options have been explored but not adopted; to be clear throughout the application whether the numbers referred to are relating to the "number of patients" or the "number of episodes"; to clarify whether or not the CAG conditions of support have been met since this impacts on both the REC approval and ongoing CAG support. **Discussion:** IGARD noted the application had been updated to reflect most of the comments previously raised. The Healthcare Quality Improvement Partnership (HQIP) had not provided adequate evidence to substantiate that public task was the appropriate legal basis. IGARD had previously queried why the University of Wisconsin School of Medicine ('University of Wisconsin') was not considered a Data Controller, along with University College London,

	since the professor based at the University of Wisconsin was referenced throughout the protocol. NHS Digital noted that the professor referenced was listed in the protocol for historic reasons, however IGARD asked that an explicit statement be included in section 5 (Purpose, Methods, Outputs) confirming that the professor from the University of Wisconsin was not involved in the current project / study. IGARD were content that Nottingham University Hospitals NHS Trust ('The Trust') had no involvement in the study, however it was not clear if the researcher were substantive employees of the Trust and seconded to the University of Nottingham ('The University') and whether this was as "employee / employer" with the University. If this was not the case, it was suggested that written confirmation be sought from the substantive employer of the seconded individual that the substantive employer would take appropriate disciplinary action in the event of a data breach by its employee during the secondment. IGARD suggested that section 5 (Purpose, Methods, Outputs) be updated to clearly differentiate between the two different references to "1%" and that it be clear whether referring to "1% mortality" or "1% prior to stroke". In addition, section 5(a) (Objective for Processing) be updated to be clear that reference to "previous strokes and heart attack…" was relating to only those patients prior to surgery, and not all patients. **Outcome Summary:** IGARD made a positive statement and were supportive of the application but were unable to recommend for approval. 1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis. 2. To confirm the role of the professor from the University of Wisconsin referred to within the application and to explicitly state why they are not involved in the project, as outlined in the protocol. 3. To clarify within section 5 the terms of researchers who are substantive employees of the Trust and seconded to the University and whether this is as "employee / employer" with the University and if not, written confirmation be sought from the substantive employer of the seconded individual that the substantive employer would take appropriate disciplinary action in the event of a data breach by its employee during the secondment. The following amendments were requested 1. To update section 5(a) to clarify the sentence starting "previous strokes and heart attack.." is relating to only those patients prior to surgery. 2. To update section 5 to clearly differentiate that the two different references to "1%" refer to either "mortality" or "prior to stroke".
2.3	<u>The University of Manchester: Evaluating the NHS Diabetes Prevention Programme (NHS DPP): the DIPLOMA research programme (Diabetes Prevention – Long term Multimethod Assessment) (Presenter: Dave Cronin) NIC-196221-K4K3Y</u> **Application:** This was a new application for pseudonymised National Diabetes Audit (NDA) for a programme to deliver an evidence-based behavioural change intervention ('the NHS DPP intervention') to patients at risk of developing diabetes, to encourage behaviour change and reduce risk of diabetes. The research programme is a mixed methods evaluation which is designed to provide: feedback regularly to NHS DPP stakeholders on the delivery and outcomes of the programme to support ongoing development and quality improvement; and a rigorous longer-term assessment of the success of the NHS DPP in meeting the aim of reducing diabetes prevalence in a way that is cost-effective and sustainable for the NHS.

	Discussion: There was a lengthy discussion with regard to the study and work packages and IGARD suggested that in order to answer questions 2 and 3 of work package 1, work needed to take place under work packages 3 and 4 since some of research questions of work package 1 could be answered by additional work under work packages 3 and 4. IGARD asked that confirmation be sought as to why the data was not being used for other work packages and was only being used for work package 1. NHS Digital confirmed that the applicant was receiving data from the UK Data Service not from NHS Digital, however IGARD suggested that an explicit statement be included in section 5 (Purpose, Methods, Outputs) confirming that the survey data was not supplied by NHS Digital, but an alternate data supplier. IGARD queried why the applicant needed to receive General Practitioner (GP) data from the NDA given they were receiving this data from the Clinical Practice Research Datalink (CPRD) dataset and suggested that section 5 be updated to reflect. In addition section 3 (Datasets Held / Requested) be updated to clearly explain the data minimisation efforts undertaken by the applicant for the NDA dataset. IGARD were unclear as to whether the applicant had informed the National Institute for Health Research (NIHR), the funder, about the changes made to the purpose of the project since the funding had been granted, and asked that confirmation be provided in writing that the work being undertaken had been reviewed and approved by the NIHR. IGARD noted that only one of the Data Controllers fair processing notices had been provided and asked that section 1 (Abstract) and section 4 (Privacy Notices) be updated to include reference to all Data Controllers under this application and provide confirmation that their fair processing notices had been checked against NHS Digital's fair processing criteria for privacy notices. IGARD noted reference to disability characteristics and queried why in particular 'learning disability' had been flagged as opposed to all or any other disabilities and asked for clarification in section 5(a) (Objective for Processing). IGARD also noted that reference to the current project was not included in section 5 and suggested that the section be updated to reflect the new current project and that it be written in a language suitable for a lay reader. IGARD noted reference to the 'Disclosure Control Policy' in section 6 (Special Conditions) and asked for clarification as to why the controls applied. **Outcome Summary:** recommendation to defer, pending: 1. Confirmation in writing that the work being undertaken has been reviewed and approved by NIHR, the funder. 2. In order to answer questions 2 and 3 of work package 1, work needs to take place under work packages 3 and 4 since some of research questions of work package 1 can be answered by additional work under work packages 3 and 4 and to confirm why the data is not being used for other work packages and only used for work package 1. 3. To update section 5 to ensure it reflects the new current project and to be also written in language suitable for a lay reader. 4. Confirmation that the survey data is not supplied by NHS Digital, but by an alternate data supplier. 5. To update the abstract and section 4 that the fair processing notices for both Data Controllers have been reviewed against NHS Digital's criteria for privacy notices. 6. To update section 3 to include an explanation of data minimisation efforts undertaken for the NDA dataset. 7. Clarification why the applicant needs to receive GP data from the NDA, given they will be receiving this data from the CPRD dataset.

	8. To update section 5 to clarify why in particular 'learning disability' has been flagged, as opposed to other disability characteristics. 9. Clarification why the NDA disclosure controls apply.
2.4	<u>King's College London**:** MR795 - Cancer Risk & Mortality in a Sample of Service Personnel Deployed to Bosnia 1992 - 1996 (Presenter: Dave Cronin) NIC-147847-P6MMR</u> **Application:** This was a new application for pseudonymised Medical Research Information Service (MRIS) data for a study to determine whether the rates of cancer and death among personnel who served in Bosnia are higher than expected. The overall aim of the study is to compare the incidence of cancer in a cohort of UK armed forces personnel who deployed to Bosnia between 1992 and 1996 and a cohort of personnel who were in service at the time but did not deploy to Bosnia. Researchers will also compare the rate of cancer in the Bosnia group with that in the general UK population. Additionally, it will be assessed whether the risk of cancer in the Bosnia group is associated with exposures to harmful materials during their deployment. **Discussion:** IGARD welcomed the application and noted the importance of this long running study. IGARD noted that a member of the study team was a member of IGARD. IGARD queried the cohorts outlined within the application and suggested that a clear statement be included at the start of section 5(a) (Objective for Processing) which outlined the source of the data for the two control groups (those termed as the 'era' group and those via the cancer registration data) and that an explicit statement be included that no data would be disseminated from NHS Digital for these two particular cohorts. IGARD were aware that thresholds would be in place in order to prevent any 'unwanted bias' or 'early publication' and queried if a specific number had been submitted to give the statistical power and make the research meaningful, and suggested that the applicant should already have the numbers of cancer and deaths required to achieve the statistical power threshold of 80% for the study, and that an explicit statement be included in section 5(a). IGARD noted reference in section 5(b) (Processing Activities) and 5(d) (Benefits) reference to key outputs, however suggested that these were in fact key milestones not final outputs and that section 5 be updated to reflect. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement (DSA). **Outcome Summary:** recommendation to approve subject to conditions 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. The following amendments were requested: 1. To update section 5(b) and 5(d) to be clear that "the key outputs" are in fact a "key milestone" not a final output The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement

	It was agreed the conditions be approved OOC by the Deputy IGARD Chair. IGARD requested that the outcome is reviewed by the NHS Digital Caldicott Guardian who may wish to formally endorse or add conditions to the recommendation.
2.5	University of Oxford: The Oxford Heart Vessels and Fat (ox-HVF) Cohort (Presenter: Dave Cronin) NIC-392669-T1F8B **Application:** This was an extension, renewal and amendment application for identifiable Medical Research Information Service (MRIS), Hospital Episode Statistics (HES), Civil Registrations and emergency Care Data Set (ECDS) for a study looking to discover new blood, genetic and imaging biomarkers that differ between patients with advanced coronary atherosclerosis and healthy individuals. The aim to progress understanding of cardiovascular disease pathogenesis leading to the development of novel markers for early disease detection, ultimately resulting in sooner, better and more efficient cardiovascular disease management in the interest of the 1.8 million people that are currently battling coronary heart disease in England. **Discussion:** IGARD noted that the HES ECDS part of the application was classed as a 'renewal' rather than an 'amendment' and NHS Digital explained that this was because HES ECDS was the new name for HES Accident & Emergency (A&E). IGARD noted the change in name, however queried if ECDS was exactly the same dataset as A&E data and suggested narrative be provided as to why it was classed as a 'renewal' rather than an 'amendment' in section 1 (Abstract). IGARD queried if the previous patient newsletters had been sent to participants of the study and suggested that an explicit statement be include in section 5 (Purpose, Methods, Outputs) including the date sent to participants. It was noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that the applicant's website be updated to comply with the GDPR, including but not limited to, clearly explaining the data controllership, the data being used, where the data is from, the processing activities undertaken, the purposes for each study, how each study interlinks, what the overarching project is and how it links to the study, to explain the cohort and to provide a mechanism for participants to withdraw consent and that a draft copy be provided to IGARD prior to publication. In addition IGARD suggested that an updated newsletter which gave details of the fair processing as outlined on the updated website be sent to all participants. If the applicant was unable to provide a written newsletter to all participants, IGARD suggested the applicant should provide a clear justification as to why a newsletter cannot be sent to participants or provide alternative means to satisfy the requirements of fair processing notice to all participants. IGARD also queried if the applicant had sought updated ethics review based on the updated protocol provided as part of the supporting documents or whether the changes made had been only considered as minor amendments. The application had previously been presented to IGARD on the 16 November 2017 and IGARD had raised the same query, however NHS Digital had confirmed they had reviewed the evidence and had approved the condition. IGARD queried the description of the end date for the ongoing study and end date of recruitment and suggested that section 1 be updated to clarify the difference between the dates relating to the ongoing study and dates relating to the ending of recruitment and that consistency in terminology be applied throughout the application. IGARD queried if the overarching project or any of the four sub-studies received European Union (EU) funding as it was not clear within the application and the study website listed such

	funding sources, it was suggested that any reference to funding met NHS Digital's appropriate standard. IGARD noted that the Oxford Risk Factors And Non-Invasive imaging (ORFAN) research study was open to multiple NHS sites for recruitment in order to achieve the expected numbers of controls for the Ox-HVF cohort, however it was not clear if this referred non-NHS sites and asked for confirmation if the information gathered relating to patients recruited in non-NHS sites would be linked to data supplied by NHS Digital. In addition it was suggested that section 5(d) (Benefits) be updated to clarify whether the cost benefits outlined applied only to the NHS. IGARD suggested that section 3(b) (Additional Data Access Requested) be updated to include the cohort numbers relating to the 4th cohort. NHS Digital noted that section 5(b) (Processing Activities) included a statement that all organisations party to the agreement must comply with the Data Sharing Framework Contract (DSFC) however IGARD suggested that an explicit statement be included that no data sharing would take place other than that outlined in the application / data sharing agreement (DSA). **Outcome Summary:** recommendation to approve subject to the following conditions: 1. Confirmation of whether the applicant has sought updated ethics review based on the updated protocol, or whether the changes made were only considered minor amendments. 2. To update the study website to provide a fair processing notice that is GDPR compliant (including but not limited to) clearly explaining the data controllership, the data being used, where the data is from, the processing activities undertaken, the purposes for each study, how each study interlinks, what the overarching project is and how it links to the study, to explain the cohort and to provide a mechanism for participants to withdraw consent. 3. To send to all participants of the study an updated newsletter which gives details of the fair processing notice as provided on the study website with similar details as point 2, or to provide a written justification as to why a newsletter cannot be sent to participants and if not, to provide alternative means to satisfy the requirements of fair processing notice to all participants. 4. To explain why the "emergency care data set" (ECDS) is classed as a "renewal" and not an "amendment" since moving from the HES A&E to HES ECDS. 5. To clarify the difference between the dates relating to the ongoing study and the dates relating to the ending of recruitment and to ensure consistency of terminology throughout the application. 6. Confirmation that neither the overarching project nor any of the four sub-studies receive any EU funding. 7. To provide confirmation if the information gathered relating to patients recruited in non NHS sites will be linked to data supplied by NHS Digital The following amendments were requested 1. To update section 5(d) to clarify whether this only applies to the NHS. 2. To update the table in section 3 to reflect the inclusion of the 4th cohort. 3. To add an explicit statement to section 5 that no sharing of data will take place other than that outlined in this application. 4. To update section 5 to confirm the date the previous patient newsletters were sent to participants. It was agreed the conditions would be approved OOC by IGARD members
3	**AOB:**

	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.

APPENDIX A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 21/06/19

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)
N/A						

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

- None