Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 9 May 2019

In attendance (IGARD Members): Nicola Fear, Kirsty Irvine (Chair), Priscilla McGuire, Eve Sariyiannidou, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Dave Cronin, Louise Dunn, Dickie Langley, Karen Myers, Vicki Williams.

1	**Declaration of interests:** Nicola Fear noted a professional link with Kings College London *[NIC-182736-Q2K7Y]* and would not be part of the discussion. It was agreed Nicola would not remain in the meeting for the discussion of that application. **Review of previous minutes and actions:** The minutes of the 2nd May 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 B).
2	**Data applications**
2.1	University of East Anglia: Falls in Care Homes (FinCH) study: Data Access Request (Presenter: Louise Dunn) NIC-195235-Q0B5T **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a trial monitoring the number of hospital admissions, A&E visits, outpatient visits and ambulance call outs for participants recruited; which will enable the research team to estimate the secondary care costs over the trial period for all participants in the study. This will enable a more accurate estimate of the cost effectiveness of the falls prevention intervention compared to usual care and will in turn help inform the evidence base used to decide which fall prevention interventions should be funded in the care home setting. NHS Digital noted that the legal basis for dissemination of the data was incorrectly noted in section 3(b) (Additional Data Access Requested) and would need updating to correctly reference s261(b)(2) as the correct legal basis for the pseudonymised data. **Discussion:** IGARD noted this was an important study looking at interventions in care homes. IGARD noted and supported the amendment outlined by NHS Digital in relation to section 3(b) being updated with the appropriate legal basis for dissemination of the pseudonymised data. IGARD had a lengthy discussion on the personal consultee consent forms and queried how the researchers had considered the legal power of the consultees to sign the forms and asked for further clarity of this in section 5 (Purpose / Methods / Outputs); noting that in the absence of an explanation on this, the legal power for the consultee to sign the forms had not been established. IGARD noted that supporting document 1, the Research Ethics Committee (REC) approval letter stated that approval was for 'NHS sites' only, and that the REC approval didn't apply to non-NHS sites since an assessment had not be undertaken, and queried the nature of the 'sites' referred to in the study and asked for confirmation that these were NHS sites. IGARD noted in supporting document 1, the REC approval letter, that the REC approved version of the protocol was version 1 and asked for clarification of the changes that had been

	made, noting that the protocol provided to IGARD for review was version 6; and also queried if the REC approval was applicable to the current version of the protocol. IGARD queried the reference in section 5(a) (Objective for Processing) and section 5(d) (Benefits) to *"At a rate of 2.5 falls per year"* and asked if this related to falls per person, per care home or other and asked for further clarity on this. IGARD noted that supporting document 9, the 2016 funding letter from the National Institute for Health Research noted some conditions needed to have been met, and asked for clarification that these had been completed; and also queried if the funding as described in the application was ongoing and asked for clarification of this. IGARD queried if the study covered England and Wales or was a UK wide study and asked for clarification in section 5 (Purpose / Methods / Outputs) of the application. **Outcome Summary:** Recommendation to defer, pending: 1. To clarify within section 5 how the researchers have considered the legal power of the consultees to sign the personal consultee consent forms, since in the absence of an explanation, the legal power for the consultee to sign the forms has not been established. 2. To confirm the nature of the 'sites' referred to in the study since the REC approval provided refers only to approval for 'NHS sites'. 3. To clarify in section 5(a) and 5(d) what the reference to "2.5 falls per year" relates to (fall per person, per care home or other). 4. To confirm if the funding conditions as outlined in supporting document 9 have been completed; and to clarify that the funding as described in the application is ongoing. 5. Since REC approved version 1 of the protocol, to provide clarification on what changes have been made in version 6 of the protocol provided for review and if the REC approval is applicable to this current version of the protocol. 6. To clarify in section 5 that the study covers England and Wales. 7. To amend the legal basis table in section 3(b) to capture the appropriate legal basis for dissemination of pseudonymised data.
2.2	<u>King's College London: MR758 - Epidemiological studies of the Porton Down veterans: an update of mortality and cancer incidence (Presenter: Stuart Blake) NIC-182736-Q2K7Y</u> **Application:** This was a new application for identifiable Medical Research Information Service (MRIS) data for a study that was originally set-up in 2003 by the University of Oxford to explore the long-term health of former servicemen who were exposed to chemical warfare agents as part of the 'human volunteer programme' at the UK government research establishment, Porton Down. The study aims to replicate the original analysis but with more recent and updated data; and to examine whether Porton Down veterans exposed to chemical warfare agent have unusual patterns of cancer incidence or mortality compared to non-Porton Down veterans. NHS Digital noted the breadth of this long running study which was unique, commencing in 1941 and that there was no other cohort of this type in the world. **Discussion:** IGARD welcomed the application and noted that this was an important and valuable study and recognised the value it brings to the research community. IGARD also noted the excellent benefits of the study outlined in section 5(d) (Benefits) of the application. IGARD noted that the University of Oxford was named as a Data Controller in the narrative of the supporting documents provided, but was not listed in section 1(b) (Data Controller(s)) of the application, and asked that this was correctly updated to include the University of Oxford

	as a Data Controller; and asked that section 5 (Purpose / Methods / Outputs) was also updated to clearly reflect this. IGARD noted that in light of the updates to the Data Controllers listed, that the application was updated to include the relevant General Data Protection Regulation (GDPR) legal basis for all of the Data Controllers. IGARD queried the cohort figure provided in the table in section 3(b) (Additional Data Access Requested) and asked that this was updated with an explanation of the split between the veterans who were exposed and those who were non-exposed, that together form the cohort. IGARD also queried the difference in cohort numbers quoted in section 3(b) and in supporting document 1, the protocol and elsewhere that shows an approximate 5,000 difference; and asked that the table in 3(b) and the rest of the application was updated with an explanation of this. IGARD queried the reference in section 3(c) (Patient Objections) that *"patient objections are addressed by section 251"* and asked that this was reviewed to ensure it reflects the actual activity taking place in respect of objections. IGARD noted the reference in section 5(b) (Processing Activities) *"…in line with the ICO guidance on data anonymisation"* and asked that this was removed as it was no longer relevant. NHS Digital noted there were no permissions for the Scotland and Northern Ireland data and so IGARD were unable to recommend for approval for Scotland and Northern Ireland data, until such times as the appropriate permissions are in place. **Outcome Summary:** recommendation to approve subject to the following conditions for the data from England and Wales only: 1. To include the University of Oxford as a Data Controller within Section 1(b) to reflect the narrative in the supporting documents. 2. To update the description of the cohort to: i) update the data access table in section 3(b) to explain the split between the exposed and non-exposed veterans that together form the cohort, and ii) to update both the table in section 3(b) and the application to explain the approximate 5,000 difference between the cohort noted in the table and the cohort in the protocol and elsewhere. The following amendments were requested: 1. To update the application to include the GDPR legal basis for all Data Controllers. 2. To update section 5 to ensure it is clear that the University of Oxford is a Data Controller. 3. To review the text in section 3(c) to ensure it reflects the actual activity taking place in respect of objections. 4. To update section 5(b) to remove reference to 'anonymization' and the 'ICO guidance'. The following advice was given: 1. IGARD were unable to recommend for approval for Scotland and Northern Ireland data, until such times as the appropriate permissions are in place. It was agreed the conditions be approved Out of Committee by the IGARD Chair.
2.3	Nottingham University Hospitals NHS Trust: Cerebrovascular accident and Acute coronary syndrome and Perioperative Outcomes study (CAPO) (Presenter: Stuart Blake) NIC-237669-T9W5N

	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. **Discussion:** IGARD welcomed the application and noted the proactive involvement of patients and the public as outlined in section 5c (specific outputs expected). IGARD noted that supporting document 4, the protocol, described the University of College London and the University of Wisconsin School of Medicine in terms suggesting that they were Data Controllers and asked for clarification in section 5 (Purpose / Methods / Outputs) why they were not considered as Data Controllers, including their involvement and role in the study. IGARD noted that Healthcare Quality Improvement Partnership (HQIP) was the Data Controller for the audit data, as outlined in supporting document 2, the s251 letter of support from the Health Research Authority (HRA) Confidentiality Advisory Group (CAG) and asked that section 1 (Abstract) was updated to clearly reflect this. IGARD also queried the role of Nottingham University Hospitals NHS Trust in the study and asked that any involvement was clarified in section 5. IGARD queried the appropriate legal basis for the flow of National Institute of Cardiovascular Outcomes Research (NICOR) data and Sentinel Stroke National Audit Project (SSNAP) data flowing into NHS Digital and asked that this was provided. IGARD queried the figures and percentages quoted in section 5a (Objective for Processing) and section 5(d) ((Benefits) and asked that a careful review was carried out on the numbers and percentages quoted to ensure accuracy; and also asked that the applicant clearly reflect the research that was going to be undertaken. IGARD also queried the quantum of data requested and asked that in order to meet the necessity test that this was justified; and that a more detailed explanation was provided clarifying why such a large amount of data was required, for example was this for sufficient statistical power or for the effective research into sub-groups. IGARD also queried what options have been explored but not adopted and asked that this be included in section 1. IGARD noted the reference to phrases such as *"…heuristic for logistic regression…"* and similar, and asked that section 5 was updated to ensure the use of technical jargon were only used where necessary and that it was also written in language suitable for a lay reader. IGARD queried if the numbers referred to in the application referred to were relating to the "number of patients" or the "number of episodes" and asked that this was made clear throughout the application. IGARD noted that supporting document 2, the Health Research Authority (HRA) Confidentiality Advisory Group (CAG) referred to some specific conditions of support and asked for clarification if these had been met, noting that this impacts on both the Research Ethics Committee (REC) approval and the ongoing CAG support. **Outcome Summary:** Recommendation to defer, pending: 1. 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. 2. To update section 1 to make clear that HQIP is the Data Controller for the audit data. 3. To clarify within section 5 any involvement of Nottingham University Hospitals NHS Trust. 4. To provide the appropriate legal basis for the flow of NICOR and SSNAP data into NHS Digital. 5. 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. 6. 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. 7. 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. 8. To be clear throughout the application whether the numbers referred to are relating to the "number of patients" or the "number of episodes". 9. 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.
2.4	<u>NHS South Norfolk CCG: DSfC - NHS South Norfolk CCG - IV (Presenter: Dickie Langley) NIC-185930-B6N0H</u> **Application:** This was an amendment application to update the storage and processing addresses of the Data Sharing Agreement (DSA) and a renewal application for identifiable Secondary Use Service (SUS) for Commissioners data, 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. **Discussion**: IGARD noted that this application had been previously recommended for approval for a period of three months on the 6 September 2018, and that their previous comments raised had not been addressed with regard to the applicant's fair processing notice. IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the General Data Protection Regulation (GDPR) and suggested that they work with NHS Digital to amend their current privacy notice including (but not limited to) being accessible and transparent, removing misleading or confusing information with regard to consent and the right to object, removing the misleading information with regard to anonymised / pseudonymised data and updating the confusing terminology with regard to the right to object and national opt outs. **Outcome Summary:** unable to recommend for approval as the outstanding condition had not been met, however NHS Digital may choose to progress this application. 1. The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including (but not limited to) being accessible and transparent, removing misleading or confusing information with regard to consent and the right to object, removing the misleading information with regard to anonymised / pseudonymised data and updating the confusing terminology with regard to the right to object and national opt outs.

2.5	University of Oxford: MR1164 - The Asymptomatic Carotid Surgery Trial (ACST-2) (Presenter: Dave Cronin) NIC-10123-M5K5H **Application:** This was an extension and renewal application for identifiable Medical Research Information Service (MRIS) data for a large international clinical trial comparing the long-term benefits of carotid endarterectomy (CEA) and carotid artery stenting (CAS) for stroke prevention. The longitudinal study benefits will help inform clinicians and patients of the long-term effects of surgery to help them make informed treatment decisions. **Discussion**: IGARD noted that this application had previously been recommended for approval for a period of three months on the 17 January 2019. IGARD noted the fair processing notice (FPN) had been updated since their last review but that supporting document 3.2, the draft FPN stated that the data *"will be held securely in Oxford"* and asked that this was amended to be more specific about the organisation that will be holding the data in Oxford. There was a lengthy discussion with regards to the consent materials provided for review. IGARD agreed with NHS Digital's review that the consent materials were not incompatible but required the revised FPN, however it was not clear if the other sub-groups had received a copy of the updated consent materials and suggested that NHS Digital satisfy themselves that they were satisfactory. IGARD queried the statement in section 5(d) (Benefits) *"The results of the first ACST trial (which compared CEA with medical therapy) changed clinical practice worldwide"* and asked that this was reconsidered in light of the likely actions to flow from the research, since it may in fact influence the development of updated guidance, for example. IGARD noted the medical terminology used within section 1 (Abstract) of the application and asked that this was clarified further. IGARD queried the lack of detail about benefits with examples of patient and public engagement. In order to be transparent for the general public when this was published within NHS Digital's data release register, IGARD noted that on renewal further information would be expected to be provided. **Outcome Summary:** recommendation to approve for those already consented in the study and have been sent the revised fair processing notice. The following amendments were requested: 1. To amend the fair processing notice to be more specific about the organisation that is holding the data in Oxford. 2. To reconsider the statement in section 5(d)(ii) that the 'results will be impactful worldwide and will change practice' in light of the likely actions to flow from the research. 3. To clarify the medical terminology used with the section 1. The following advice was given: 1. IGARD advised when the application returns to IGARD for renewal, IGARD would expect to see further information with regard to yielded benefits and outputs. **Outcome Summary:** In respect of the other sub-groups, the recommendation to approve is conditional upon NHS Digital reviewing the relevant updated consent materials and deeming them satisfactory.
3	**AOB**

	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.
3.1	As part of their oversight role, IGARD discussed the following matters: • Overview Framework including a review of NHS Digital's dashboard • Precedent and standards review • Future education session / items

Independent Group Advising on Releases of Data (IGARD): Out of committee report 03/05/19

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-213403-P3R8Q	NHS Improvement	04/04/2019	1. To insert appropriate security assurance wording relating to the use of cloud storage 2. To provide clarification in section 1 and section 5 on the definition of 'Consultants'. 3. To provide further clarity in section 1 and section 5 on what is meant by 'unit level activity, whether this refers to the Consultant's own activity only and the level and the type of data the Consultant with have access to. 4. To provide further clarity in section 1 and section 5 what is meant by 'designated organisation' with reference to NHS Trust and the implications if the designated organisation is not a Trust. 5. To update section 5 to reflect the sub-licensing arrangements as outlined in the sub-licensing agreement.. 6. To update section 1 and section 5 to provide clarity on the level of data that Consultants will have access to on the dashboard. 7. To provide confirmation that the data held is restricted to care and treatment activity in English hospitals only. 8. To clarify the role of CMA and The Royal National Orthopaedic Hospital NHS Trust as Data Processors under this application.	OOC by quorum of IGARD members.	OOC by quorum of IGARD members.	

			9. To clarify whether Advanced 365 Ltd is only listed as a storage location and if so to insert a special condition in section 6 stating that Advanced 365 Ltd will not access data held under this agreement.			
NIC-287049-F7M1P	195 CCGs (class Action application)	11/04/2019	1. To clarify in Section 5(b) that processing under this application excludes any data of patients registered in or resident in Wales. 2. To clarify the legal basis for the collection of PROMs data. 3. To remove reference to the national HES data from the application, since it was no longer required as part of this application.	OOC by IGARD Chair	OOC by IGARD Chair	

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

- None