Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 9 August 2018

Members: Sarah Baalham, Anomika Bedi, Jon Fistein, Kirsty Irvine (Chair), Eve Sariyiannidou.

In attendance: Garry Coleman, Louise Dunn, Victoria May, Karen Myers, James Smith, Kimberley Watson.

Apologies: Joanne Bailey, Nicola Fear.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The outcomes of the 2nd August 2018 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meetings. **Out of committee recommendations** There were no outstanding out of committee recommendations.
2	**Data applications**
2.1	<u>Institute of Cancer Research: MR400 - Cohort Study of People with Insulin Treated Diabetes (Presenter: James Smith) NIC-147748-XD18S</u> **Application:** This was an extension and renewal application for identifiable Medical Research Information Service (MRIS) data for a national study of mortality and cancer incidence in patient with insulin-treated diabetes. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD suggested for audit proposes that NHS Digital produce a supporting document outlining the HRA CAG s251 support for the cohort described in the application. IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 be updated to clearly state that the application privacy notice 'does not' meet the criteria. IGARD suggested that a special condition be included within the application that on renewal the application would be expected to provide a copy of their current ethics approval letter. IGARD queried what the applicant had done to minimise the use of identifiable data and asked that a special condition be included in the application noting that upon return the applicant must clarify what they have done to reduce the use of direct identifiers. **Outcome:** recommendation to approve from such time as ONS data has moved to NHS Digital controllership and subject to the following conditions: 1. To produce a supporting document outlining HRA CAG s251 support for the cohort outlined in the application. The following amendments were requested: 1. To include a special condition stating that on renewal of this application, the applicant will be required to produce a copy of their current ethics approval. 2. To update section 4 to state the applicant's fair processing notice 'does not' meet the NHS Digital's fair processing criteria for privacy notices

	3. To include a special condition noting that upon return the applicant must clarify what they have done to reduce the use of direct identifiers. It was agreed that the condition would be agreed OOC by the IGARD members.
2.2	Institute of Cancer Research: MR287 - Study of Twins (Presenter: James Smith) NIC-147923-P5DTX **Application:** This was an extension and renewal application for identifiable Medical Research Information Service (MRIS) data for a national study looking at cancer in twins. Gaining information on familial and genetic risks of cancer is important, this matters to patients, and to health care and screening of their relatives, they can also give important insights more widely into the causes, hence prevention of cancer, **Discussion:** IGARD suggested for audit proposes that NHS Digital produce a supporting document outlining the HRA CAG s251 support for the cohort described in the application. IGARD queried what the applicant had done to minimise the use of identifiable data and asked that a special condition be included in the application noting that upon return the applicant must clarify what they have done to reduce the use of direct identifiers. IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 be updated to clearly state that the application privacy notice 'does not' meet the criteria. IGARD noted that not all the information within section 5(c) related specifically to this application and asked for this to be amended to ensure all the information relates only to this application. **Outcome:** recommendation to approve subject to the following condition: 1. To produce a supporting document outlining HRA CAG s251 support for the cohort outlined in the application. The following amendments were requested: 1. To include a special condition stating that on renewal of this application, the applicant will be required to produce a copy of their current ethics approval. 2. To include a special condition noting that upon return the applicant must clarify what they have done to reduce the use of direct identifiers. 3. To update section 4 to clearly state the applicant's fair processing notice 'does not' meet the NHS Digital's fair processing criteria for privacy notices 4. To amend section 5(c) to ensure all information relates specifically to this application. It was agreed that the condition would be agreed OOC by the IGARD members
2.3	Medical Research Council Clinicals Trials Unit: MR1470 - Application for access to ONS Mortality data for the STAMPEDE trial: Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy. (Presenter: Kimberley Watson) NIC-59873-D8C6G **Application:** This was a new application for pseudonymised Medical Research Information Service (MRIS) data. The STAMPEDE trial is a randomised controlled trial which is looking at adding therapies to standard care for men with high-risk prostate cancer starting long-term hormone therapy for the first time. The trial's definitive primary outcome measure is overall survival and intermediate primary outcome measure is failure-free survival. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD queried who would have access to the data and asked that section 5(b) be updated to explicitly state that there will not be any access to the data by any third parties.

	IGARD discussed the various versions of patient consent and patient information material which were produced as supporting documents and being relied on by the applicant to satisfy the common law duty of confidentiality. It was IGARD's view that the materials did not meet the requisite common law standard. One example of where the consent material fell short was where the research participant expressly consented to the researcher checking contact details should they lose contact but was silent on the fact that the participant's medical history would be regularly collected. Though IGARD disagreed with the conclusion reached, they asked that the standard abstract wording be amended where reference is made to patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations to those that have consented". IGARD subsequently queried whether the applicant might consider seeking section 251 support to cover all of the participants involved in the study, or to update the consent material and go back to the cohort. IGARD suggested NHS Digital might wish to consider liaising with CAG to discuss the principles raised by the consent materials linked to this application. IGARD noted that all Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month. IGARD noted that the information within the application in relation to the ethics approval differed to information in the supporting documents and asked for evidence of clarification of the scope of the ethics approval. IGARD noted that the legal basis in the data flow diagram in supporting document 1 was incorrect and asked for this to updated. IGARD noted that the applicant was listed in section 1 of the application as a Data Controller and Data Processor but that this be updated to clearly state that the applicant was a Data Controller who also processed data. **Outcome:** Recommendation to defer, pending: 1. To explicitly state within section 5(b) that there will not be any access to the data by any third parties. 2. To update the abstract to amend references to patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented". 3. To update section 4 with the standard wording "All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". 4. To provide evidence of clarification of the scope of the ethics approval. 5. To update the legal basis within the data flow diagram in supporting document 1. 6. The application should be updated to clarify that University College London are a Data Controller who also processes data. The following advice was given: 1. The applicant might consider seeking section 251 support to cover all participants or, if practicable, to update the consent material and go back to the cohort.

	2. NHS Digital might consider liaising with CAG in respect of the general principles raised by the consent materials.
2.4	University of Warwick: Prevention of Shoulder Problems Trial: exercise to prevent shoulder problems in patients undergoing breast cancer treatment. (Presenter: Kimberley Watson) NIC-75485-J3R9B **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) for the PROSPER Trial which is a multi-centre pragmatic two-arm Randomised Control Trial (RCT) examining an intervention to prevent shoulder problems in patients following breast cancer surgery. Following surgery, it is common for women to suffer a range of postoperative symptoms in the upper arm and shoulder which can persist for many years after treatment. The intervention in PROSPER builds upon existing evidence that exercise programmes following surgery can improve functional outcomes and reduce complications. The purpose of the PROSPER trial is to examine whether such a programme is clinically and cost-effective in comparison to usual care. **Discussion:** IGARD noted that the consent materials make reference to further consent being sought for the type of processing outlined in the application. Accordingly, IGARD recommended that the applicant should recontact the cohort to seek further consent for this new processing, as anticipated by the existing consent materials. IGARD noted that all Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month. NHS Digital advised there was an error within abstract and 'supporting document 2' that is referred needed amending to 'supporting document 3'. **Outcome:** Unable to recommend for approval 1. The applicant should recontact the cohort to seek consent for this new processing, as anticipated by the existing consent materials 2. To update section 4 with the standard wording "All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". 3. To amend reference to supporting document 3 within the abstract and replace with supporting document 2
2.5	The Health Foundation: RENEWAL Extension to NIC-321421-Z4V4N - Funding pressures, phenotyping hospitals, penalising readmission and analysing factors associated with A&E performance in England (Presenter: Louise Dunn) NIC-15411-C9Z9L **Application:** This was an amendment and renewal application for The Health Foundation to add UK Cloud as a storage location and to add the final 2015/16 year for Admitted Patient Care (APC), Outpatient (OP), Accident & Emergency (A&E) and Critical Care (CC), for the case of OP 2015/16 will include a new bespoke variable consult type; month and year of death (and bridge file with Hospital Episode Statistics (HES)) from the Office for National Statistics (ONS) mortality data. The additional data request will enable the applicant to complete ongoing work packages and to allow peer review of work produced so far. This was previously deferred by IGARD pending clarification of the legal basis for the dissemination of data under GDPR; the Fair Processing section to be amended to include the new standard wording; section 5 to be updated to be explicit how the Institute of Fiscal Studies are involved; clarification within section 5 whether "all researchers with access to data" are substantive employees of the Health Foundation; update section 5(a) to include explanatory

	background information suitable for the lay reader; Clarification why applicant requires month and year of death in addition to fact of death for patients. **Discussion:** IGARD noted that detail about the Legitimate Interest(s) relied upon should be included within the narrative of section 5 and reference should be made within the abstract that NHS Digital has considered the Legitimate Interest Assessment (LIA) produced by the applicant and deemed that it satisfactorily evidences GDPR requirements. IGARD noted that historic phrasing was being used in section 4 Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month. IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5(b) of the application that the applicant will not link data in this application. **Outcome:** recommendation to approve subject to the following condition: 1. To include narrative within the abstract and the purpose section of the application explaining the Legitimate Interests relied on and to make reference in the abstract that NHS Digital has considered the LIA produced by the applicant. The following amendments were requested: 1. To update section 4 with the standard wording "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". 2. Confirmation within section 5(b) of the application that the applicant will not link the data. It was agreed that the condition would be agreed OOC by the IGARD members.
2.6	<u>The Health Foundation: Future demand pressures on mental health services in England (Presenter: Louise Dunn)</u> <u>NIC-179115-S0R1W</u> **Application:** This was a new application for pseudonymised Mental Health Services Dataset (MHSDS) to analyse trends in mental health activity at a detailed level. Figures suggest that over a five-year period from 2008/09 to 2013/14 social care expenditure on adults with mental health needs aged between 18 and 64 reduced in cash terms from £1.2 billion to £1.1 billion. **Discussion:** IGARD noted that detail about the Legitimate Interest(s) relied upon should be included within the narrative of section 5 and reference should be made within the abstract that NHS Digital has considered the Legitimate Interest Assessment (LIA) produced by the applicant and deemed that it satisfactorily evidences GDPR requirements. IGARD noted that historic phrasing was being used in section 4 Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". IGARD queried how the applicant would achieve their stated outputs with the two years of data they were requesting and if this was sufficient to complete their analysis and asked for further clarity on this.

	IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5(b) of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement. IGARD queried what 'The Cloud' was and suggested that a more detailed explanation was provided within section 5(b) to clarify what the 'The Cloud' storage facility is. **Outcome**: recommendation to approve subject to the following conditions: 1. To include narrative within the abstract and the purpose section of the application explaining the Legitimate Interests relied on and to make reference in the abstract that NHS Digital has considered the Legitimate Interest Assessment (LIA) produced by the applicant. 2. To provide further clarity on how the applicant can achieve their stated outputs with the two years data requested. The following amendments were requested: 1. To update section 4 with the standard wording "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". 2. Confirmation within section 5(b) of the application that the applicant will not link the data further 3. To make reference to and provide brief explanation of 'The Cloud' storage facility within section 5(b). It was agreed that the conditions would be agreed OOC by the IGARD members.
2.7	<u>Royal Brompton and Harefield NHS Trust: Epidemiology and Prognosis in Acute Myocarditis (Presenter: Kimberley Watson) NIC-144568-D7G6V</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data linked to Office for National Statistics (ONS) mortality data. There is a public interest in sudden cardiac deaths and cardiac transplantation amongst young individuals and a need to update the understanding of the epidemiology and prognosis of myocarditis. Early detection through improved awareness would make a significant contribution to individual patient care. **Discussion:** IGARD welcomed the application and noted the importance of the research. IGARD queried why the applicant was requesting the volume of national data given the limited outputs of the research and asked for the applicant to provide a clear justification. IGARD also queried why the wide age range of national data was being requested given the limited outputs and asked for a clear justification. IGARD noted that a further explanation was required within section 5(d) to clarify how clinical guidelines at a national level will be informed and benefit from this research and not just limited to the applicant's NHS Trust. IGARD queried what the routes to dissemination was to wider stakeholders outside academic activity and asked for this to be clarified within section 5(c). IGARD noted that historic phrasing was being used in section 4 Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period

	after obtaining the personal data, but at least within 1 month". IGARD noted their endorsement of NHS Digital's review of HQIP's privacy notice and suggested they update in line with GDPR requirements. IGARD noted that there was a reference to 'anonymised' data in paragraph 4, page 7 of the application and suggested this was removed. IGARD noted that the ONS terms and conditions were noted within the application and suggested these be removed. IGARD noted that in supporting document 1, the HRA Ethics Tool, the applicant answered "no" to bullet one in question set 2 *"Will your study involve research participants identified from, or because of their past or present use of services (adult and children's healthcare within the NHS and adult social care), for which the UK health departments are responsible (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls?"* and asked for further clarity on the reason for this answer. IGARD queried what the current position was in relation to funding from the "Alexander Jansen Foundation" and asked for further clarity on this. **Outcome:** Recommendation to defer, pending: 1. In light of the limited outputs, justify the number of years and volume of national data requested 2. In light of the limited outputs, justify the wide age range of national data requested 3. Further detail in section 5(c) about the routes to dissemination to wider stakeholders outside academic activity 4. Explanation in 5(d) as to how national clinical guidelines will be informed by this piece of work (and not limited to the applicant's NHS Trust) 5. To update section 4 with the standard wording "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". 6. Remove reference to 'anonymised' data in paragraph 4, page 7 of the application 7. Remove the ONS terms and conditions 8. Explanation of the answer of "no" to the question in bullet one, question set 2 of the HRA Ethics Tool 9. Further information on funding from the "Alexander Jansen Foundation".
2.8	<u>The Royal Marsden NHS FT: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Victoria May) NIC-190996-C4P9G</u> **Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset. The independent Cancer Taskforce set out a vision for improving services, care and outcomes for everyone with Cancer. Cancer Alliances, which have been set up across England, are key to driving the change needed across the country to achieve the Taskforce's vision providing the opportunity for a different way of working to improve and transform Cancer services. **Discussion:** IGARD noted that it was not clear within the application who the Data Controller is and asked for the applicant to consider whether NHS England or another party involved should also be added as Joint Data Controller.

	IGARD queried the background information on the Cancer Alliance, specifically who the parties are within the Cancer Alliances and what the governance and contractual arrangements are in place between the Cancer Alliance actors and asked for this to be explicitly noted within the application. IGARD noted that there was limited information within the application noting how members of the Cancer Alliance will access the data and asked for this to be clarified. IGARD queried what the relationship was between the CCGs and Cancer Alliances and asked for clarification on the possible duplication of access to data. IGARD noted that further clarification was required on how the controls on access to data will be implemented and enforced. **Outcome:** Unable to recommend for approval 1. The applicant to consider whether NHS England or other parties involved should also be added as joint Data Controllers 2. To explicitly list the parties in the relevant Cancer Alliance and the governance and contractual arrangements as between the Cancer Alliance actors 3. To clarify how the members of the Cancer Alliance will access the data 4. To clarify the interplay between CCGs and Cancer Alliances and any possible duplication of access to data 5. To clarify how the controls on access to data will be implemented and enforced
3	**AOB**