Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 25 July 2019

In attendance (IGARD Members): Kirsty Irvine (Chair), Priscilla McGuire, Eve Sariyiannidou, Geoffrey Schrecker.

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

Not in attendance (IGARD Members): Anomika Bedi, Maria Clark, Nicola Fear, Maurice Smith.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The outcomes of the 18th July 2019 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting. The minutes of the 18th July 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	University of Liverpool: MR1298: UK Lung Cancer Screening (UKLS) Trial Lung Cancer Registry and Mortality data for consented individuals (Presenter: Dave Cronin) NIC-19237-R3T6S **Application:** This was an amendment and renewal application for identifiable Medical Research Information Service (MRIS) for a study of lung cancer screening in the UK, with the aim of providing the information required for an informed decision about the introduction of population screening for lung cancer. The pilot study recruited 4,061 participants and was completed in 2016. The decision had been made not to continue to a full trial, but the applicant requested data to produce outputs for the UK National Screening Committee. The research project intends to be part of a wider international effort to address the critical issue of earlier detection of lung cancer, required to address the single largest cause of cancer-related mortality. NHS Digital noted that the data sharing agreement (DSA) would be shortened to one year to enable the draft programme level agreement standard to be published. NHS Digital noted that the applicant had provided a draft privacy notice and that this was currently being reviewed against NHS Digital's fair processing criteria for privacy notices, with a commitment by the applicant to amend, where necessary, and publish. NHS Digital noted that section 5(b) (Processing Activities) wording with regard to duty of confidence should be amended. NHS Digital noted reference to the Office for National Statistics (ONS) data and suggested this should be updated.

	Discussion: IGARD agreed that section 5(b) should be amended regarding the references to Duty of Confidence and 'ONS' data. IGARD noted that supporting document 3.1 'UKLS protocol v.14 28Jan19' detailed the involvement of a number of collaborators in the study design and outputs and further noted that the collaborators were part of the study team. However, these collaborators were not listed in the application as joint Data Controllers or Data Processors. It was suggested that a clear narrative be provided as to why the collaborators listed were not considered either joint Data Controllers or Data Processors for the UK study, in light of the information provided. IGARD also noted that the University of Liverpool's Data Security and Protection Toolkit (DSPT) standards had been met but that there was reference to the NHS Digital security manager completing the security review; NHS Digital confirmed that that the security manager had reviewed satisfactorily and this information had been amended within section 1 (Abstract). IGARD also noted that although The Royal Liverpool and Broadgreen University Hospitals NHS Trust had formally requested to be removed from the role of the co-sponsor, it was still listed in the most recent protocol as one. In addition, co-sponsorship and joint data controllership are two separate functions, and The Royal Liverpool and Broadgreen University Hospitals NHS Trust still appeared in supporting document 3.1 as co-investigators. It was requested that clarification be provided as to why the hospital was now not considered a joint Data Controller. IGARD noted that section 2(c) Territory of Use was listed as England and Wales, however it was not clear if record level data was being shared with the United States of America (USA) and the European Economic Area (EEA) and it was suggested that NHS Digital ensure the territory of use was compatible with the proposed data sharing. IGARD noted reference to 'lung cancer incidence' and suggested that this terminology be updated to 'lung cancer mortality'. It was noted that although the study was based on residence in Merseyside and Cambridgeshire, recruited individuals may have moved subsequent to recruitment and suggested reference to '*all UK data is requested*' be updated to more accurately reflect '*UK data relating to this cohort is requested*'. The pilot had not progressed to a full trial due to lack of funding and NHS Digital noted that the applicant wanted to produce more value from the pilot. IGARD noted that the applicant had already received data to produce outputs for the UK National Screening Committee over the past three years and discussed the added value of the applicant to continue to hold and receive data for this purpose. IGARD noted it was not clear within the application if the data being shared was derived data or if was record level / pseudonymised data and suggested that section 5 (Purpose / Methods / Outputs) be updated to correctly reference that only derived data will be shared with a clear narrative supporting this throughout, and that reference to record level data and pseudonymised data sharing be removed. IGARD noted references in the application to access to record level pseudonymised data in the *United Kingdom Lung Cancer Screening Trials (UKLS) database* by 'named researchers', 'collaborators' and 'qualified staff' and queried who these were and whether they included individuals from projects undertaken in the USA and EEA. IGARD also noted additional references in the application to data from the clinical database including information derived from the data and requested a clear explanation of what type and level of data the applicant intended to share. IGARD was unclear about the type and purpose of the proposed linkages and requested that section 5 be updated to clearly outlined what data linkage was being

	undertaken, what datasets were being linked and the purpose of any data linkage through a clear narrative which linked back to the collaborators listed in supporting document 3.1. IGARD suggested that section 5(d) (Benefits) be updated to more accurately reflect realistic and achievable measurable benefits. **Outcome Summary:** recommendation to approve subject to the following conditions in respect of the continuation of the work that is being undertaken to hold and process the existing data flows to produce outputs for the UK National Screening Committee. 1. To clarify why The Royal Liverpool and Broadgreen University Hospitals NHS Trust are not considered joint Data Controllers. 2. To clarify why the other collaborators named in the protocol are not considered joint Data Controllers or Data Processors. The following amendments were requested: 1. To update section 5(b) to amend the reference to the Common Law Duty of Confidentiality. 2. To update section 5(b) to remove reference to 'ONS' data. 3. To amend the application throughout to ensure that there is a consistent narrative that derived data is proposed to be shared, particularly by removing references to pseudonymised or record level data sharing. 4. To update the application to amend the references from "cancer incidence" to "cancer mortality". 5. To update the reference in section 5(a) from "all UK data" to "UK data relating to this cohort". 6. To revise section 5(d) of the application to set out more realistic and achievable measurable benefits. IGARD were unable to recommend for approval for any aspect relating to the sharing of data or data linkage. 1. The sharing of derived data only is not reflected within the application which makes numerous references to the sharing of pseudonymised or record level data. 2. It is not clear within the application what the data linkage is, what datasets will be linked and the purpose of any data linkage. It was agreed the conditions would be approved OOC by IGARD members.
2.2	<u>Glasgow Caledonian University: Prolong20+ Longitudinal study of pelvic floor dysfunction and relationship to childbirth: Access to current names, addresses and mortality statuses. (Presenter: Dave Cronin) NIC-250100-R3W1G</u> **Application:** This was a new application for identifiable Medical Research Information Service (MRIS) data for a study investigating the long-term consequences of childbirth on urinary incontinence (UI), faecal incontinence (FI), pelvic organ prolapse and sexual dysfunction, known collectively as pelvic floor dysfunction (PFD). PFD in women in middle to later life is common, detrimental to health and well-being, and increasing in prevalence. There is increasing evidence to suggest that these problems may be consequences of, or are exacerbated by, pregnancy and delivery and in 1993-1994 8,000 women living in Aberdeen, Birmingham and Dunedin (New Zealand) took part in the ProLong study, three months after giving birth. The ProLong+ aims to contact the UK-based ProLong study participants. **Discussion:** IGARD noted that this application was for list cleaning purposes and suggested that section 5(a) (Objective for Processing) be updated to explicitly state that the application was for list cleaning only and did not relate to any data that may flow relying on consent. It was

	suggested that when the application for Hospital Episode Statistics (HES) was submitted to NHS Digital that the consent materials should be updated to include, but not limited to, an express statement detailing the three Data Controllers (the applicant, the University of Aberdeen and the University of Birmingham) and how they were involved in the study, and to clearly describe this study as part of the wider international study including those involved in the study. IGARD also suggested that the applicant may wish to seek advice from the Royal College of Obstetricians and Gynaecologists Women's Voice Panel with regard to their patient information sheet and questionnaire, to seek their informed perspective as an engaged group of patients. It was also noted that any further application for HES should be brought back to a future IGARD meeting and suggested that for any future application for HES the applicant should consider the involvement of the University of Aberdeen and University of Birmingham as joint Data Controllers and provide a clear narrative. IGARD noted that one of the conditions of support from the Health Research Authority Confidentiality Advisory Group (HRA CAG) was to provide wider patient notification materials within the relevant outpatient clinics at Birmingham Women's NHS Foundation Trust and asked that written confirmation be provided that all the conditions of support had been met, but in particular the displaying of information posters within relevant clinics. **Outcome Summary:** recommendation to approve subject to approve subject to the following condition 1. To provide written confirmation that the HRA CAG conditions of support have been met, in particular, the displaying of information posters within the relevant clinics. The following amendments were requested: 1. To amend section 5(a) to explicitly state that the application is for a List Clean only and does not relate to any data that may flow relying on consent. The following advice was given: 1. IGARD advised that they would wish to review any further application(s) when the applicant applies for HES data. 2. IGARD advised that when the application for HES data is submitted, consideration should be given to including the University of Aberdeen and the University of Birmingham as joint Data Controllers. 3. IGARD advised that when the application for HES data is submitted the consent materials should be updated to include (but not limited to) an express statement of who the three joint Data Controllers are; and to clearly describe this study's part in the wider international study. It was agreed the conditions would be approved OOC by the IGARD Chair.
2.3	<u>King's College London: End of life care outcomes for adults with serious mental illness (Presenter: Dave Cronin) NIC-144761-Y3X9Y King's College London</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) and Civil Registrations data for a research project exploring the end of life care circumstances of adults with a diagnosis of serious mental illness (SMI). The project aims to achieve a clear picture of where patients with SMI die and their health care utilisation at end of life and assess what demographic and/or clinical factors are associated with place of death in this patient group.

	This current project is to continue and expand upon previous work carried out at a local level which explored end of life care outcomes in adults with SMI in South London, with this project to assess end of life care at a national level to demonstrate or not if patients with SMI face inequalities in care at end of life. **Discussion:** IGARD noted that this was to expand at a national level a previous local project carried out by the South London Mental Health Trust, SLaM but asked that a clear statement be included in section 5(a) (Objective for Processing) that the applicant was not using or linking any datasets from that local study. IGARD noted their concerns of coding of mental health diagnosis when those with SMI were admitted to hospital for physical ailments and suggested that NHS Digital discuss with the applicant the quality of coding for adults with SMI to ensure they received the necessary quality and quantity of data which would enable them to carry out the proposed processing in order to realise the stated benefits. IGARD queried the statement "…*demonstrating whether there are inequalities compared to the general population*…" and suggested that NHS Digital discuss with the applicant how the propose to obtain a relevant comparable cohort in the general population for a control group. IGARD noted an erroneous sentence in section 5(d) (Benefits) "The results." and suggested the sentence be completed or removed. **Outcome Summary:** recommendation to approve subject to the following condition 1. To make a clear statement in section 5(a) that the applicant is not using or linking any datasets from the local study. The following amendment were requested: 1. To update section 5(d) to complete the sentence that starts "The results…" The following advice was given: 1. IGARD advised NHS Digital discuss with the applicant their concerns about relying on the quality of coding for adults with serious mental illness and to ensure that they will receive the necessary quality and quantity of data to enable them to carry out the proposed processing in order to realise the stated benefits. 2. IGARD advised NHS Digital discuss with the applicant how they will identify a comparable cohort in the general population. It was agreed the conditions would be approved OOC by IGARD Chair
2.4	<u>Imperial College London: SCAMP: Study of Cognition, Adolescents, and Mobile Phones MR1439 (Presenter: Stuart Blake) NIC-27085-C5L5G</u> **Application:** This was an amendment application for identifiable Hospital Episode Statistics (HES) data, Medical Research Information Service (MRIS) data and Diagnostic Imaging Dataset (DIDs) for a study which aims to address current scientific uncertainties by investigating whether the use of mobile phones and / or other technologies that use radio waves may affect adolescents cognitive or behavioural development, as well as exploring wider health outcomes. **Discussion:** IGARD welcomed the application which came for advice on the consent materials. IGARD noted that participants had previously consented using parental consent and that there was no new recruitment to the study, which involved 39 participating schools in and around London following several thousand secondary school pupils.

	NHS Digital referenced published standard 8 'GDPR Consent' (though not relevant to this application, as GDPR Consent was not a legal basis relied upon), which was silent with regard to capacity for those aged 15, but noted that standard 7b 'Duty of Confidentiality' was still in final draft and did not detail how to assess capacity of those aged 15; it was suggested that standard 7b be updated with additional guidance notes relating to consent and children / young people and, in particular, ascertaining capacity of young people. IGARD noted that the applicant suggested in supporting document 7.3 'IRSA Version 5.11' that "*As the General Data Protection Regulation (GDPR) and Data Protection Act 2018 lowered the age of consent to 13 years of age, it is reasonable that SCAMP give permission for data linkage at the age of 15*" but noted this was reference to GDPR "*lowering the age of consent*" was factually incorrect. IGARD suggested that NHS Digital seek the advice from the Caldicott Guardian with regard to the issue of assessing capacity in the context of the duty of confidence and in particular to the capacity of 15 year old participants and that the Caldicott Guardian be provided with the relevant information to make an informed decision, and should the Caldicott Guardian take a different view to that of IGARD, that a legal analysis be provided as a supporting document detailing the decision taken. IGARD noted that the Caldicott Guardian should oversee that the duty of confidence has been appropriately satisfied. IGARD noted that in the case of young people aged 16 and 17 their legal capacity to consent for treatment, as confirmed in statute, did not extend to research, so suggested that parental consent was sought for those aged under 16 and for those young people aged 16 and 17, that their consent be sought along with parental assent. IGARD reviewed the consent materials provided by the applicant and were labelled as supporting documents 7, 7.1, 7.2, 7.3, 7.4 and 7.5 and made specific comments on the consent materials related to those aged 16 to 17 years of age, in particular: 1. That the consent materials be amended to remove potentially coercive elements for instance to state that any invitation to a careers event did not automatically enrol them in any future data collection and that it was not linked a consent decision and to quantify the value of the reward scheme to participate in the research 2. To remove reference to 'anonymised' data, since this was a misleading statement and to state instead that the data did not directly identify the individual. 3. To remove reference to consent for any future research since an individual cannot give generic consent at this age to research that may have different requirements, or to be explicit that the researchers can only hold the contact details for participants and that the researchers may contact those participants in the future about further research. **ACTION:** IGARD Secretariat to forward a copy of the draft 7b standard 'Duty of Confidentiality' to NHS Digital colleagues in DARS for information and prior to its sign off by the Caldicott Guardian (see also AOB). **Outcome Summary:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed. 4. On the face of the evidence presented, IGARD's advice is that parental consent is sought for those aged under 16 and that for those aged 16 and 17 the young person's consent be sought plus parental assent. 5. IGARD suggested that NHS Digital present IGARD's advice to the Caldicott Guardian and seek formal advice from the Caldicott Guardian on the questions

	posed, especially the issue of capacity (and particularly in regard to the capacity of 15 year old participants) and that should the Caldicott Guardian's take a different view to IGARD, IGARD would be grateful to receive a legal analysis supporting that decision. 6. IGARD suggested that Standard 7b Duty of Confidence be updated with additional guidance notes relating to consent and children/young people, to support both NHS Digital and applicants. IGARD provided specific comments on the consent materials related to those aged 16-17: 7. That the consent materials be amended to remove potentially coercive elements for instance to state that any invitation to a careers event did not automatically enrol them in any future data collection and that it was not linked a consent decision and to quantify the value of the reward scheme to participate in the research 8. To remove reference to "anonymised" data and to state instead that the data does not directly identify the individual. 9. To remove reference to consent for any future research; or to amend to clarify that the researchers can hold contact details and may contact participants in the future about further research.
2.5	<u>University College London: Evaluating the Family Nurse Partnership in England (Presenter: James Humphries-Hart) NIC-136916-B7D5C</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), Civil Registrations and Medical Research Information Service (MRIS) data for a longitudinal research study aiming to evaluate the real-world implementation of the Family Nurse Partnership (FNP) in England. FNP is an intensive early home visiting programme for first time young mothers, delivered by trained nurses aiming to improve maternal and child outcomes by providing support throughout pregnancy and until the child's second birthday. The study aims to evaluate the real-world implementation of FNP in England with findings from the study helping policy makers decide whether FNP should be offered to families in their local setting. **Discussion:** IGARD noted the valuable research being undertaken and welcomed the application. IGARD queried section 8(b) (Funding Sources) and reference to the EU / International programme was listed as 'EU'(European Union) with the awarding institution listed as 'NIHR' (National Institute of Health Research) and suggested that, if the study is part of an EU funded project, section 5 (Purpose / Methods / Outputs) be revised to reference IGARD's previous advice on the 'criteria for assessing applications – EU funded', a published document on IGARD's webpage from September 2017. IGARD noted the two cohorts: approximately 975,000 mothers aged between 13-24 who delivered a baby between 1 April 2010 and 31 March 2017; and those within the FPN with a cohort size of approximately 25,000 and suggested a clear narrative be provided why the larger control group was necessary rather than a smaller stratified sample for comparison. It was also suggested that the applicant consider the needs and nature of the cohort with regard to the dissemination and content of the transparency materials and the accessibility of those materials. IGARD also queried how the research aims would be realised when the cohort data disseminated under the application related only to the mother and not the infant / child and suggested that NHS Digital may wish to discuss with the applicant whether the data set requested under this application was the best fit for the proposed processing and

	this be clarified in section 5. It was also suggested the applicant consider to additional pathways of dissemination of the outputs to ensure maximum impact and reach. IGARD noted that supporting document 2 'FNP protocol v9' detailed the involvement of a number of collaborators in the design and outputs and that they were part of the study team but not listed in the application as joint Data Controllers or Data Processors; and suggested that a clear narrative be provided confirming their role and how they fit with the study and why they are not considered joint Data Controllers and / or Data Processors. IGARD noted that the conditions of support from the Health Research Authority Confidentiality Advisory Group (HRA CAG), supporting document 4.3, and asked that written confirmation be provided that all the conditions of support had been met, in particular work being undertaken with regard to patient and public involvement and engagement. It was not clear within the documentation provided how the FNP cohort data was created and the legal gateway to process the data and suggested that a clear narrative be given, including any linkage to data held under another data sharing agreement (DSA). IGARD were unclear, since this was listed as a new application to IGARD, how the table in section 3(a) (Data Access Already Given) had been populated and asked for clarification including the data minimisation efforts undertaken. NHS Digital noted this was a subset of data held under another programme of work and it was suggested that this narrative be included in Section 5(a) (Objective for Processing). It was also suggested that the data minimisation column in section 3(b) (Additional Data Access Requested) be completed. **Outcome Summary:** recommendation to defer, pending: 1. To clarify whether the study is part of an EU funded project and, if that is the case, section 5 should be revised to reflect recent IGARD advice on the criteria for assessing applications which are EU funded. 2. To clarify how the FNP cohort data was created and what the legal gateway is for the applicant to process that data. 3. To provide further details of the collaborators listed in the protocol and confirm their role, how they fit with the study and why they are not considered joint Data Controllers and / or Data Processors. 4. To provide written evidence that the HRA CAG conditions of support have been satisfied. 5. To clarify how the data in section 3(a) has been populated including the data minimisation efforts undertaken, for example that this is a subset of data held under another Data Sharing Agreement and that this narrative also be included within section 5(a). 6. To complete the data minimisation column in table 3(b). 7. To explain how the benefits of the research will be realised when the cohort data disseminated under this application only appears to relate to the Mother and not the infant/child. IGARD suggested that NHS Digital discuss with the applicant whether the data set requested is the best fit for the proposed processing. 8. To provide a clear narrative why the large control group (975,000) is necessary rather than a significantly smaller stratified sample for comparison. 9. To consider the nature of the cohort with regards to the dissemination and content of the transparency materials. The following advice was given:

	1. IGARD suggested that the applicant give consideration to additional pathways of dissemination of the outputs to ensure the impact and reach of the outputs is maximised
4	**AOB:**
4.1	**HQIP Legal Basis** IGARD discussed the ongoing matter with regard to the legal basis for the Healthcare Quality Improvement Partnership (HQIP) and noting the AOB item from 4 July, agreed that further work be undertaken including a draft paper for NHS Digital to consider and how IGARD would consider future applications to IGARD in relation to this specific issue.
4.2	**Duty of Confidentiality / Data Protection** IGARD noted that standard 7b 'Duty of Confidentiality' was in final draft and awaiting sign off by the Caldicott Guardian but that additional notes may be required by both NHS Digital and the applicants to distinguish between: a) the requirements of the duty of confidence and data protection; and b) the requirements of consent with regard to children and young people in the context of the duty of confidence in the following different settings - treatment - therapeutic research - non-therapeutic research - clinical trials of medicines Such guidance could include the provision of additional notes, checklists and a flow chart. **ACTION:** IGARD Secretariat to forward a copy of the draft 7b standard 'Duty of Confidentiality' to NHS Digital colleagues in DARS for information and prior to its sign off by the Caldicott Guardian and to provide feedback as to whether additional guidance notes would be helpful. **ACTION:** DARS to review the current suite of finalised standards and provide a list of those standards which may need a future review and additional guidance notes to support both NHS Digital and the applicant. 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.
4.3	

Independent Group Advising on Releases of Data (IGARD): Out of committee report 19/07/19

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-359603-D2Q6M	Care Quality Commission	04/07/2019	1. To update the application setting out the steps taken by CQC to review the use of identifiers and an analysis of whether the amount of identifiable data held and requested continues to be necessary.	OOC by IGARD Chair	OOC by IGARD Chair	N/A

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

- None