

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 21 February 2019

Members: Anomika Bedi, Maria Clark, Nicola Fear (Acting Chair), Priscilla Maguire,

In attendance: Stuart Blake, Louise Dunn, Rachel Farrand, Vicki Williams.

Apologies: Sarah Baalham, Joanne Bailey, Kirsty Irvine, Eve Sariyannidou.

Observers: Maurice Smith

1	<p>Declaration of interests:</p> <p>Nicola Fear noted professional links to King's College London [NIC-387635-C9Y0W] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 14th February 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p>
2	Data applications
2.1	<p><u>Royal National Orthopaedic Hospital NHS Trust: Getting It Right First Time programme - hosted by the Royal National Orthopaedic Hospital (Presenter: Rachel Farrand) NIC-14440-Q2G4W</u></p> <p>Application: This was a renewal, amendment and extension application for pseudonymised Hospital Episode Statistics (HES) data to address incorrectly selected filters for the 2017/18 data and extend / renew the data sharing agreement (DSA) and remove UCL from the application.</p> <p>The Getting It Right First Time (GIRFT) programme aims to support improvements in clinical efficiency for 35 workstreams, 12 of which are surgical, 19 of which are medical and the remainder of which are cross-cutting. The HES data is used by the programme to calculate a range of activity and quality metrics for these specialities at hospital and clinical commissioning groups (CCG) summary level, which feed into the programme's outputs.</p> <p>The application was been previously considered on the 1st November 2018 when IGARD had deferred pending: to provide clarification in section 5 why UCL are not considered a Data Controller since they are an independent evaluator and applying for NIHR funding; to confirm within section 5 who the GIRFT team are and in what way they are separate to the UCL CLARC team, and additionally confirm which organisations form the makeup of each team; update section 5 to be explicit on the identity of the other collaborating organisations in the network as well as to explain how the other collaborating institutes within the network outlined in the application are involved, including their role and any data they may have access to; to update the abstract with reference to Article 6 to reflect recent discussion between NHS Digital and IGARD to correctly list the appropriate legal basis; to clarify within the abstract that the Chair of the Programme has overall responsibility for the processing of the data and remove the sentence which starts "it ultimately reports to the Secretary of State for Health..." since it is not relevant for this application; the application should be amended to confirm that funding is in place and provide relevant evidence; to provide further examples of measurable benefits and outputs for the work UCL</p>

	<p>have undertaken as part of this research; to confirm that any organisation that had previously received NHS Digital data but now was no longer involved in processing it had confirmed to NHS Digital that they no longer held any NHS Digital data and that appropriate data destruction notices has been issued.</p> <p>Discussion: IGARD noted that the application had been updated to reflect most of the comments previously made.</p> <p>IGARD noted that University College London (UCL) who had previously been included within the application had now been removed, however IGARD noted that section 5(b) (Processing Activities) should be updated to clearly describe the current position with regard to UCL.</p> <p>Outcome: recommendation to approve</p> <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. To amend section 5(b) to clearly describe the current position with regards to University College London, as outlined in the abstract.
2.2	<p><u>King's College London: MR1308 - Sentinel Stroke National Audit Programme (SSNAP) (Rachel Farrand) NIC-387635-C9Y0W</u></p> <p>Application: This was an amendment and renewal application for pseudonymised Hospital Episode Statistics (HES) and identifiable Medical Research Information Service (MRIS) data for a programme that measures both the processes of care provided to stroke patients, as well as the structure of stroke services against evidence-based standards.</p> <p>The overall aim of SSNAP is to provide timely information to clinicians, commissioners, patients, and the public on how well stroke care is being delivered so it can be used as a tool to improve the quality of care that is provided to patients.</p> <p>NHS Digital noted that section 3 should be updated to correctly list the legal basis.</p> <p>Discussion: IGARD noted that the Healthcare Quality Partnership (HQIP) had not provided adequate evidence to substantiate that public task was the appropriate legal basis. IGARD also suggested that NHS Digital work with the IG Advisor to IGARD to correctly list the Data Protection Act (DPA) 2018 schedule 1 Part 1 references against each of the Article 9 legal basis cited and clearly describe how the schedule conditions are met.</p> <p>IGARD noted that one of the Health Research Authority Confidentiality Advisory Group (HRA CAG) specific conditions of support provided as a supporting document noted that if HQIP were relying on consent to disclose information onwards that it should be in line with the requirements of the General Data Protection Regulations (GDPR) and DPA 2018. In addition, it was suggested that NHS Digital clarify that a different lawful basis had been established for HQIP for the Welsh data processed and linked between the period December 2012 and August 2018.</p> <p>IGARD noted and supported the amendment to section 3(a) (Data Access Already Given) and section 3(b) (Additional Data Access Required) to be clear that the legal basis was 'mixed' since both s251 support and consent were being relied upon.</p> <p>IGARD noted that the language used in the abstract and section 5 contained a lot of technical information which may not be accessible to a lay reader and asked that this be amended.</p> <p>Outcome: unable to recommend for approval:</p> <ol style="list-style-type: none"> 1. HQIP have not provided adequate evidence to substantiate that public task is the appropriate legal basis. <p>The following amendments were requested:</p>

	<ol style="list-style-type: none"> 1. To correctly list the DPA 2018 schedule 1 Part 1 references against the Article 9(2)(i) legal basis cited and clearly describe how the schedule conditions are met 2. To amend section 3(a) and 3(b) to be clear that the legal basis was 'mixed' since both s251 and consent were being relied upon 3. To revise the abstract and section 5 in terms suitable for a lay reader. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. NHS Digital should confirm that a different lawful basis has been established for HQIP for Welsh data processed and linked between December 2012 and August 2018 as per the CAG specific condition of support letter provided.
2.3	<p><u>Cambridge University Hospital NHS FT: MR1474 - UK-PBC Project - cohort datasets (Presenter: Stuart Blake) NIC-360208-K1T4F</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES) data, identifiable Diagnostic Imaging Dataset (DIDs) and Medical Research Information Service (MRIS) data for a UK-wide project that is broadly aimed at improving the understanding of Primary Biliary Cholangitis (PBC), which is a rare, chronic liver disease.</p> <p>The UK-PBC is divided into 3 Work strands; work strand 1 is involved in developing a comprehensive PBC cohort for complete clinical characterisation; work strand 2 is focused on the immunology behind PBC; and work strand 3 is involved in delivering clinical trials of relevance to patients, patient education and modelling costs and benefits associated with PBC treatment. This application refers to work strand 1 only.</p> <p>NHS Digital noted that applicant's Data Protection Act date had expired.</p> <p>Discussion: IGARD welcomed the application and the worthwhile study, and noted the work undertaken by NHS Digital and the applicant. IGARD noted the applicant's DPA had expired and suggested the correct date be updated within the application.</p> <p>IGARD noted that the application was in relation to work strand 1 and that this was well explained in section 5, however suggested for transparency that a clear narrative be given on how work strand 1 fitted into the wider Immune-Mediated Inflammatory Disease Biobanks in the UK project which was referenced in the funding letter provided as a supporting document. It was also suggested that on renewal, the applicant provide further detail within section 5 of how work strand 1 had impacted on the development of work strand 2 and work strand 3.</p> <p>It was also noted that the funding letter noted a number of organisations and companies involved in the wider project who were referenced within section 5(a) along with a number of other organisations. It was suggested that because the funding letter was relevant to this application that the roles and responsibilities of these organisations and companies be clearly explained within section 5(a) (Objective for Processing). It was also suggested that a special condition be included that there will be no onward sharing of NHS Digital data, since this application and agreement did not grant approval for any data sharing.</p> <p>IGARD noted that recruitment for this UK wide study commenced in 2007 however the ethics review and protocol provided as supporting documents were dated 2015 and referenced the involvement of a number of organisations and companies. It was not clear of their involvement within the application and how it aligned with the wider Immune-Mediated Inflammatory Disease Biobanks in the UK project, and suggested that section 5(a) (Objective for Processing) be updated to clarify.</p> <p>IGARD noted that the patient information sheet and application referenced 'major life events', however it was not clear to a lay reader what this term meant and suggested that section 1(a)</p>

	<p>(Abstract) and section 5 be updated to clearly explain. It was also suggested that the applicant's fair processing notice be updated to define what was meant by a 'major life event'.</p> <p>IGARD queried who would be accessing the data and NHS Digital confirmed it would be the lead investigators based at the two lead organisations, plus their teams. IGARD suggested that section 6 (Special Conditions) include an additional special condition that only the two lead investigators and their teams who were substantive employees of Cambridge University Hospital NHS Foundation Trust (FT) or the University of Cambridge, the two lead organisations, could access the NHS Digital data under this application and data sharing agreement.</p> <p>IGARD suggested that section 1(a) (Abstract) be updated to remove the '(2)' after General Data Protection Regulation (GDPR) Recital 52.</p> <p>Outcome: recommendation to defer</p> <ol style="list-style-type: none"> 1. To provide a clear narrative on how this component of the project (work strand 1) fits into the wider Immune-Mediated Inflammatory Disease Biobanks in the UK project referred to in the funding letter provided as a supporting document 2. With reference to 1 above, to clarify the roles and responsibilities of the organisations and companies stated in the funding letter and listed within section 5a. 3. With reference to 1 above, to clearly describe how the protocol and ethics approval included with this application align with the wider Immune-Mediated Inflammatory Disease Biobanks in the UK project 4. To clearly explain within the abstract and section 5 what is meant by 'major life events'. 5. To include a special condition that there will be no onward sharing of NHS Digital data. 6. To include a special condition that the only individuals accessing the NHS Digital data are the lead investigators and their teams who are substantive employees of Cambridge University Hospital NHS FT or the University of Cambridge, the two lead organisations 7. To correctly update the Cambridge University Hospital NHS FT DPA expiry date 8. The abstract should be updated to remove "(2)" after GPDR Recital 52. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested on renewal that further detail be included in section 5 of how work strand 1 has impacted on the development of work strands 2 and 3. 2. IGARD suggested that the applicant update their fair processing notice to clearly define what is meant by 'major life events', and for transparency.
2.4	<p><u>University of York: English Indices of Deprivation 2019 - Health Deprivation and Disability Domain indicators (Presenter: Louise Dunn) NIC-219055-K4F8R</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data for the purpose of calculating and validating indicators of health deprivation for each lower-layer super output area (LSOA) in England. The resulting health deprivation indicators will form part of the English Indices for Deprivation 2019 and will be published as official statistics by the Ministry of Housing, Communities and Local Government.</p> <p>The application was been previously considered on the 24th January 2019 when IGARD had had deferred pending: the applicant and NHS Digital to consider the appropriate Data Controller(s) / Data Processor(s) in light of the parties involved in the research as outlined in the supporting documents provided and to include the appropriate GDPR legal basis for each party; when clarifying the appropriate Data Controller(s) / Data Processor(s) it should be clearly explained within section 5 of the application the roles and responsibilities of those parties</p>

including their role in the design of and the responsibility of the project; to delete the paragraph referencing the Higher Education and Research Act 2017 since it is not relevant to this application; to update the abstract on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD regarding the legal basis including (but not limited to) reference to public task to clearly pinpoint the statutory function for the Ministry of Housing, Communities and Local Government and clearly linking this to the purpose set out in the application; if the applicant is relying on Article 9(2)(g) the abstract should be updated to clearly describe how the schedule conditions are met under DPA 2018, and reference to Article 89(1) should be removed; to correctly update the University of York DPA expiry date; to revise section 5(a) in terms suitable for a lay reader; dependent on the parties involved with this project, consideration should be given to whether this application is commercial or not.

Discussion: IGARD noted that the application had been updated to reflect most of the comments previously made.

IGARD noted that clarification of the roles of the Data Controller(s) and Data Processor(s) had been included in section 1(a) (Abstract) however suggested that this text regarding the roles and responsibilities of the Ministry of Housing Communities & Local Government, the University of York and Oxford Consultant for Social Inclusion Limited be included within section 5, for transparency.

IGARD suggested that the abstract should be further amended with regard to Articles 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD regarding the legal basis including, but not limited to, reference to the public task legal basis wording for the Ministry of Housing, Communities and Local Government in relation to the provision of statistics to include "...one of its responsible is also in relation to statistics relating to deprivation, housing and homelessness, local government, finance planning, performance and land use". In addition, it was suggested that this provision be reflected within the University of York's legal basis and that both organisation's legal basis be included within section 5(a) (Objective for Processing), for transparency.

IGARD suggested that a special condition be included within section 6 (Special Conditions) that only record level linkages are those permitted under this application or data sharing agreement. It was further suggested that a special condition be included that only the substantive employees of the University of York could access NHS Digital data.

IGARD suggested that repeated text in section 7 (Ethics Approval) be removed.

Outcome: recommendation to approve

The following amendments were requested:

1. To include within section 5 the text from the abstract relating to the roles and responsibilities of the Ministry of Housing Communities & Local Government, the University of York and Oxford Consultant for Social Inclusion Limited, for transparency.
2. To update the abstract section on Articles 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including (but not limited to) updating the public task legal basis wording for the Ministry of Housing Communities & Local Government in relation to the provision of statistics and reflect this provision within the University of York's legal basis, and to also reflect the public task legal basis for both organisations within section 5.
3. To include a special condition that the only record level linkages are those permitted under this application or agreement.
4. To include a special condition that the only individuals accessing the NHS Digital data are substantive employees of the University of York.

2.5	<p><u>Imperial College London: MR700 - SINGLE SIGMOIDOSCOPY SCREENING IN PREVENTION OF BOWEL CANCER (The UK Flexible Sigmoidoscopy Screening Trial; UKFSST) (Presenter: Louise Dunn) NIC-148071-QHNM8</u></p> <p>Application: This was an amendment application for identifiable Medical Research Information Service (MRIS) data for a randomised controlled trial examining the long-term effect of a single flexible sigmoidoscopy (FS) screen on colorectal cancer (CRC) incidence and mortality, which is now in long-term follow-up, including adding one more study objective and include the use of UKFSST data to validate findings.</p> <p>The primary aim is to quantify the reduction in incidence and mortality from CRC resulting from a single FS screen at age 55-64 years with colonoscopy surveillance for those found to have high-risk polyps.</p> <p>Discussion: IGARD noted that the Health Research Authority (HRA) London South East Research Ethics Committee had referenced and approved version 4 of the UKFSST research protocol however IGARD noted that this had not been provided as a supporting document and asked that a copy be provided since it supported the scope of the amendment.</p> <p>IGARD noted that a copy of the HRA Confidentiality Advisory Group (CAG) register had been provided however it was not clear if the proposed amendment had been included within the applicant's annual review to HRA CAG and suggested that a copy of the most recent CAG annual review submission be provided.</p> <p>It was noted that the study received mortality data from the Office for National Statistics (ONS) prior to it transferring to NHS Digital, IGARD suggested that section 5 be updated to clearly reflect the inclusion of ONS mortality data and that since ONS were no longer able to share mortality data for health research, NHS Digital had taken the decision to include the historic ONS mortality data under this application and data sharing agreement. IGARD welcomed this approach.</p> <p>IGARD suggested, on renewal, that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public including specific examples of patient / public engagement.</p> <p>Outcome: recommendation to approve subject to the following conditions</p> <ol style="list-style-type: none"> 1. To provide a copy of version 4 of the UKFSST protocol as referenced in the most recent ethics approval, since it supported the scope of the amendment. 2. To provide a copy of the recent CAG Annual Review submission. <p>The following amendment was requested:</p> <ol style="list-style-type: none"> 1. Section 5 should be updated to reflect the inclusion of the historical ONS mortality data, now provided by NHS Digital. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. IGARD suggested that on renewal further details of pathways of dissemination of the outputs and benefits be provided including examples of public / patient engagement. <p>It was agreed the conditions would be approved OOC by the IGARD Chair.</p>
3	<p>AOB</p> <p>None</p>

Independent Group Advising on Releases of Data (IGARD): Out of committee report 15/02/19

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-147829-5K4QP	University of Cambridge	10/01/2019	<ol style="list-style-type: none"> 1. To clarify the subjects of the derived pseudonymised data being sharing onwardly; and if the data relates to living persons, to include an amendment in section 5 clarifying that there will be no attempt to re-identify by recipients of derived data. 2. To remove reference to the 47 consented participant sub-cohort who do not appear to be covered under the s251 support documents provided. 	IGARD Members	Quorum of IGARD Members	N/A

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

- None