Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 6 September 2018

Members: Anomika Bedi, Nicola Fear, Jon Fistein, Kirsty Irvine (Chair), Eve Sariyiannidou.

In attendance: Dave Cronin, Louise Dunn, Rachel Farrand, James Humphries-Hart, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Apologies: Sarah Baalham, Joanne Bailey.

1	Declaration of interests:
	Nicola Fear noted a professional link to the research team at Imperial College London (NIC- 311095-K1Q0B) but noted no specific connection with the application and it was agreed this was not a conflict of interest.
	Review of previous minutes and actions:
	The minutes of the 30 August 2018 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	Cardiff University: Building Blocks Trial – Data Archive (Presenter: Dave Cronin) NIC-313754- G6X4Z
	Application: This was a new application to retain data already disseminated for five years for storage and back up purposes only, with no further data being requested, which will allow studies to comply with good clinical practice and regulations on retaining data for periods of time to allow for scrutiny of the findings and in some cases future research.
	This application was previously brought to IGARD on the 18 January 2018 for advice where a short-term Data Sharing Agreement extension was given pending further work on the 'Data Archive' Agreement template.
	NHS Digital noted that the applicant's Data Sharing Agreement with NHS Digital had expired.
	Discussion: IGARD noted that the discussion was not on the basis that this was a template application, as previously presented, but as a standalone application, noting that the application should still set out how it complies with the legal, policy and common practice framework that regulates data retention. IGARD noted that the application had not been updated to reflect most of the comments previously made on the 18 January 2018.
	IGARD queried if the applicant would revisit the archived data and NHS Digital noted that the agreement permitted them to store the data but no further processing, however IGARD suggested that there were statements within section 5 that indicated otherwise and suggested that it be explicitly stated that only archiving was permitted under this application and that any further processing of the data would be subject to a further application. Reference was made to earlier Department of Health guidance and the relevant clinical trials legislation which regulates data retention It was also suggested that the applicant demonstrate how they have adopted appropriate security measures which are required for archiving including details about the measures and access controls in place.

	IGARD also noted inconsistency in the use of the phrase 'personal data' throughout the application and particularly to exclude pseudonymised data from the description of personal data and suggested that it updated throughout, including clearly describing within section 5(b) the processing of personal data. IGARD noted that the applicant stated that a Data Protection Impact Assessment (DPIA) was not required, however IGARD suggested that the applicant consider the ICO's screening tool especially the section listing the instances when a DPIA is required and which may provide specific points to support their statement that a DPIA is not required and update the application to provide further information about how the conclusion was reached that a DPIA was unnecessary.
	IGARD noted their comments were without prejudice to any future applications or additional issues which may arise from other applications being fully reviewed.
	Outcome: unable to recommend for approval
	 To provide further clarify on why the applicant has stated within the application that a Data Protection Impact Assessment (DPIA) is not required as judged against the ICO's screening tool and provide specific points to support this statement. To update the application to reflect the legal, policy and common practice framework that regulates data retention. To explicitly state within section 5 that only archiving is permitted under the application and any further processing would be subject to a future application.
	4. Further clarify within section 5(b) to clearly describe the processing of personal data to ensure that the description also includes pseudonymised data and ensure consistent and accurate use of the phrase 'personal data' throughout the application.
	 To demonstrate how the applicant has adopted the appropriate security measures including the access controls in place.
	IGARD noted the importance of the research undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, and in light of this it was suggested that NHS Digital might wish to consider a short-term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.
2.2	The Nuffield Trust: Understanding and improving healthcare quality and health outcomes for children and young people (Presenter: Dave Cronin) NIC-204228-D8J4D
	Application: This was a new application for pseudonymised Hospital Episode Statistic (HES) data for a programme of work focusing on Children and Young People (CYP) including a longitudinal analysis looking at variations in hospital activity and CYP health outcomes.
	NHS Digital noted reference to 'a select number of other individuals' should be removed
	NHS Digital noted that a supporting document had been provided to IGARD which was not relevant and that it had now been removed from the CRM holder.
	NHS Digital noted that standard wording in section four of the application should be updated to reference '1 month'.
	Discussion: IGARD noted that standard wording in section 4 be updated to clearly reference 1 month: "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 noted reference to 'a select number of other individuals in section 5(b) and suggested reference to sharing data with third parties be removed from the application. It was also suggested that that reference to 'unnamed third parties' be removed from section 5(b).
	IGARD queried what the criteria and scope was of the proposed projects outlined in the application and asked for this to be clarified along with the framework criteria for future projects and to state how they will fall within the same scope. It was also suggested that section 5(b) be updated to clearly state how the data will be used within the projects outlined, what data is being used and how the data will be appropriate minimised.
	IGARD noted that the planned outputs within the annual report should updated within the renewal application and suggested the applicant may wish to consider including more information about the partners involved, the relationships and data accessed.
	It was suggested the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice including (but not limited to) revising the wording to make clear that members of the public do not have to first approach the Nuffield Trust if they had a complaint about the use of their data and more clarity re what data is being used for this particular project.
	Outcome: recommendation to approve subject to the following conditions:
	 To clarify the criteria for assessment and the scope of the proposed projects and to set out a framework criteria for those projects and how they will all fall within the same scope.
	 A clear explanation of how the data can be used within the projects, what data is used and how it will be appropriately minimised in section 5(b).
	The following amendments were requested:
	 Reference to be made to the planned annual report within section 5 and confirmation that the outputs outlined in the annual report will be updated within the application upon renewal.
	 To remove reference to 'a select number of other individuals' in section 5(b) and any other reference to data being shared with third parties throughout the application. To remove reference to 'unnamed third parties' in section 5(b). Section 4 of the application be updated to refer to the privacy notice being published within 'one month' of receipt of data not 'three months'.
	The following advice was given:
	 IGARD suggested that applicant may wish to update their FPN including (but not limited to) revising the wording to make clear that members of the public do not have to first approach the Nuffield Trust if they had a complaint about the use of their data and more clarity re what data is being used for this particular project
	It was agreed the conditions would be approved OOC by IGARD members
2.3	Imperial College London: MR1342 – Nottingham Study of Neurotic Disorder – 30-year follow- up (Presenter: Louise Dunn) NIC-311095-K1Q0B
	Application: This was an extension and renewal application for Medical Research Information Service (MRIS) data and list cleans for the last phase of a 30-year randomised controlled trial in which patients with anxiety and depressive disorders seen in general practice psychiatric clinics agreed to receive different randomised treatments and have both short and long-term follow up. The last phase of the trial is to determine cause of death in the cohort of patients.

	Discussion: IGARD welcomed the application and noted the importance of the work being undertaken.
	IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice, including being accessible. NHS Digital noted that the applicant would be visiting with the cohort and would be able to share an updated physical copy of the privacy notice. In light of this recommendation, IGARD suggested that standard wording within section 4 of the application be removed.
	IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5b of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement.
	IGARD queried who would have access to the data outlined in the application and asked that section 5(b) be updated to explicitly state that there will be not be any access to the data by any third parties, except those permitted under this application / data sharing agreement.
	IGARD noted that within the application the length of the study was 30 years, however the ethics approval provided as a supporting document noted a study length of 28 years. IGARD asked that clarification be sought of the length of the study and that ethics approval was still in place.
	IGARD noted that the application stated that 'date of death' was required in order to ensure that no communication was made with participants who had died and 'cause of death' required to support the analytical part of the work, however it was not explicit within the application and suggested that clarification be sought and updated within section 5.
	Outcome: recommendation to approve subject to the following condition
	1. The applicant to provide a fair processing notice that is compliant with the notice requirements under the GDPR, and before data can flow.
	The following amendments were requested:
	 To clarify the length of the study (28 or 30 years) and confirm that ethics approval is still in place.
	 To clarify that the researcher is requesting 'date of death' data to prevent any communication being issued to deceased participants as well as 'cause of death' to support the analytical part of the work.
	3. To explicitly state within section 5(b) that data will not be accessed by any third parties, other than those permitted under this application.
	 Confirmation within section 5(b) of the application that the applicant will not link the data further and the only data linkages are those permitted under this application. To remove the fair processing notice standard wording from section 4in light of the condition to approval to this application.
	It was agreed the condition would be approved OOC by IGARD Members.
2.4	London School of Economics and Political Science (LSE): Effects of competition and incentives on productivity, quality and efficiency of NHS providers (Presenter: Kimberley Watson) NIC-354497-V2J9P
	Application: This was an amendment and renewal application for pseudonymised Hospital Episode Statistic (HES) and Patient Reported Outcome Measures (PROMs) data to analyse the impact of on-going NHS reforms implemented between 2000 and present day. The reforms were primarily associated with the introduction of two Acts of Parliament (the National

Health Service Act 2006 and the Health and Social Care Act 2012) that changed both the organisational and payment structures of the NHS.

NHS Digital noted a reference to 'IGARD minutes' within the abstract should be updated to correctly reference 'DAAG minutes'.

Discussion: IGARD noted that the collaboration agreement provided at supporting document 1 referred to the London School of Economics, the University of York and the University of Kent and asked that it be clarified why the Universities or York and Kent were not listed as joint Data Controllers. IGARD asked for further elaboration in section 5 on how the collaborating universities were involved, including their role in the design and performance of the project and suggested a copy of the original collaboration agreement in place between the collaborating organisations be provided to NHS Digital. IGARD noted that access to data is not a determining factor of data controllership.

IGARD noted that both 'doctoral candidates' and 'honorary associates' would have access to the data for research and that they would not have a contract of employment with LSE. IGARD noted that doctoral candidates would automatically sign up the University's terms and conditions for which they were working for, however were not clear what an 'honorary associate' was and asked that further information about the role and scope be provided. IGARD also noted that the honorary contracts provided referenced the Data Protection Act 1998 and suggested that the applicant may wish to update. Also, IGARD asked for clarify who LSE Health is, as noted in the application.

IGARD suggested that an explanation be provided of the involvement of The Health Foundation (referred to in supporting document 2) and an explanation of the alignment of the purpose of the funding (introducing health care technology innovations into the NHS) with the purpose of the application (the impact of policy development and NHS reforms on patient outcomes). It was also noted within supporting document 1 the funding arrangement expires in December 2018 and suggested the application be updated to indicate that funding will be in place for the duration of the project.

IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that it be updated to include (but not limited to) reference to public task and public interest and appropriate justification under GDPR to the reference of University of London within the abstract.

IGARD queried why the applicant had requested additional data and suggested that a clear explanation be given within section 5 why the additional data sets and data years were required for each project.

IGARD also queried who would have access to the data and asked that section 5(b) be updated to explicitly state that no record level data will be accessed by third parties, except those permitted under this application / data sharing agreement.

IGARD noted that the data was being moved to a new location however it was not clear whether the data would be moving on the existing server to the new storage location or if the data was being moved to a new server at the new storage location. IGARD asked if NHS Digital were content that the appropriate security steps had been undertaken by the applicant and that it be clear within section 5 if data was transferring on the old server or being transferred to a new server.

IGARD noted the 'DPA Registration' special condition within section 6 that the Data Controllers and Data Processors under this agreement are required to pay a data protection fee to the ICO under the Data Protection (Charges and Information) Regulations 2018.

	Outcome: unable to recommend for approval.
	 To clarify the roles of the University of Kent and the University of York and provide further explanation why they are not considered joint Data Controllers, in light of the collaboration agreement provided as supporting document 1. Provide an explanation of the 'Honorary Associate' role and scope. To clarify who LSE Health is. To explain the involvement of the Health Foundation and the alignment of the purpose of the funding with the purpose of the application.
	 To update the abstract to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to public task and public interest including appropriate justification under GDPR to the reference of University of London within the abstract.
	 For each of the four purposes outlined in the application to clearly describe within section 5 the requirement for the additional data sets and data years. To provide confirmation that no record level data will be shared with third parties unless fully justified within the application.
	8. To confirm within section 5 if the data will be moved on the existing server to the new storage location or if the data will be moved to a new server at the new storage location and to provide confirmation that appropriate security steps have been undertaken by the applicant for which NHS Digital are content.
2.5	University of East Anglia: Request for data including addresses and ages to contact healthy controls for participation in STEC case-control study (Presenter: Rachel Farrand) NIC-171083- Q8R4B Application: This was a new application for identifiable Medical Research Information Service (MRIS) data for a Shiga-toxin E.coli (STEC) case-control study which is needed to reflect current causes of infection in England so better prevention strategies can be developed. Discussion: IGARD welcomed the application and were supportive of the work being undertaken using NHS Digital data
	undertaken using NHS Digital data. IGARD queried the identification of the potential 'healthy' control group population of 50,001 and it was noted that this would generate a response rate of approximately 4% which was as expected. IGARD noted that the control group outlined in the abstract be updated to 'Case Controlled Study'.
	IGARD noted that the table in section 3 should be updated to reference the legislation being relied on in addition to s.261(7).
	IGARD suggested that a special condition be included within the application that explicitly states that only Public Health England (PHE) will have access to and process the data under this application / data sharing agreement.
	Outcome: recommendation to approve
	The following amendments were requested:
	 To explicitly state within the special conditions section that only Public Health England (PHE) will have access to and process the data. Amend section 3(b) to include, in addition to s.261(7), the additional supporting legislation being relied upon. To amend reference to the 'Case Study' in the abstract to state 'Case Controlled Study'.

2.6	University of Leicester: MR1275 – The United Kingdom Aneurysm Growth Study (UKAGS) (Presenter: Dickie Langley) NIC-148437-C9YSC
	The application was withdrawn by the presenter
2.7	NHS Norwich CCG: DSfC – NHS Norwich CCG – IV (Presenter: James Humphries-Hart) NIC- NIC-185910-D9W1Y
	Application: The application had previously been presented to IGARD on the 19 April 2018 and IGARD had recommended for approval subject to conditions: The CCG should update their privacy notices in line with NHS Digital's nine criteria for privacy notices before data can flow.
	NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 19 April 2018 and re-reviewed as per usual process.
	Discussion: IGARD recognised the work the CCG had undertaken to update their fair processing notice, however it was noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice including being accessible and transparent.
	Outcome: recommendation to approve for 3 months.
	The following advice was given:
	1 The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including being accessible and transparent.
	It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority and advised that IGARD would wish to review this application when it comes up for renewal.
2.8	NHS South Norfolk CCG: NHS South Norfolk CCG - IV (Presenter: James Humphries-Hart) NIC-185930-B6N0H
	Application: The application had previously been presented to IGARD on the 19 April 2018 and IGARD had recommended for approval subject to conditions: The CCG should update their privacy notices in line with NHS Digital's nine criteria for privacy notices before data can flow.
	NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 19 April 2018 and re-reviewed as per usual process.
	Discussion: IGARD recognised the work the CCG had undertaken to update their fair processing notice, however it was noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice including being accessible and transparent.
	Outcome: recommendation to approve for 3 months.
	The following advice was given:
	1 The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including being accessible and transparent.

	It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority and advised that IGARD would wish to review this application when it comes up for renewal.
2.9	NHS West Norfolk CCG: NHS West Norfolk CCG - IV (Presenter: James Humphries-Hart) NIC-185937-D7J1Y
	Application: The application had previously been presented to IGARD on the 19 April 2018 and IGARD had recommended for approval subject to conditions: The CCG should update their privacy notices in line with NHS Digital's nine criteria for privacy notices before data can flow.
	NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 19 April 2018 and re-reviewed as per usual process.
	Discussion: IGARD recognised the work the CCG had undertaken to update their fair processing notice, however it was noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice including being transparent.
	Outcome: recommendation to approve for 3 months.
	The following advice was given
	1 The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including being transparent.
	It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority and advised that IGARD would wish to review this application when it comes up for renewal.
2.10	NHS North Norfolk CCG: NHS North Norfolk CCG – IV (Presenter: James Humphries-Hart) NIC-185940-J1W0Y
	Application: The application had previously been presented to IGARD on the 19 April 2018 and IGARD had recommended for approval subject to conditions: The CCG should update their privacy notices in line with NHS Digital's nine criteria for privacy notices before data can flow.
	NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 19 April 2018 and re-reviewed as per usual process.
	Discussion: IGARD recognised the work the CCG had undertaken to update their fair processing notice, however it was noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice including being accessible and transparent.
	Outcome: recommendation to approve for 3 months.
	The following advice was given:
	1 The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including being accessible and transparent.
	It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority and advised that IGARD would wish to review this application when it comes up for renewal.

3	AOB
	IGARD Standard Wording
	IGARD noted the Director Data Dissemination's wish for IGARD to review standard wording within the minutes and IGARD agreed to update the standard wording used for appropriate applications from: "It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority" to "It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority" to "It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority" to "It was the view of IGARD that this application would not be appropriate for renewal by IAO and Director delegated authority and advised that IGARD would wish to review this application when it comes up for renewal."

Independent Group Advising on Releases of Data (IGARD): Out of committee report 31/08/18

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- 147923- P5DTX	Institute of Cancer Research	09/08/2018	 To produce a supporting document outlining HRA CAG s251 support for the cohort outlined in the application. 	OOC by IGARD Members	Quorum of IGARD Members	The following amendment (in bold) could be made within the abstract: "Based on the above and conversations with CAG , the DAO is content that PIAG 3-07(j)/2002 covers each of the above cohort studies. To reiterate, only the one listed as cohort study 4 is relevant to this DARS application."
NIC- 147748- XD18S	Institute of Cancer Research	09/08/2018	1. To produce a supporting document outlining HRA CAG s251 support for the cohort outlined in the application.	OOC by IGARD Members	Quorum of IGARD Members	The following amendment (in bold) could be made within the abstract: "Based on the above and conversations with CAG , the DAO is content that PIAG 3-07(j)/2002 covers each of the above cohort studies. To reiterate, only the one listed as cohort study 4 is relevant to this DARS application."
NIC- 15411- C9Z9L	The Health Foundation	09/08/2018	 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. 	OOC by IGARD Members	Quorum of IGARD Members	Insert into the abstract the following in red text and drop a quick confirmation back to the mailbox: "The LIA was carried out by The Health Foundation using the ICO template and has been reviewed by NHS

						Digital . The Health Foundation concluded that they can rely on legitimate interests for this processing. A summary of the decision justification is provided below;"
NIC- 56872- T9B0J	University of Warwick	02/08/2018	 Confirmation there is no flow of data from NHS Digital to ICNARC / NICOR and confirmation there is no flow of data from ICNARC / NICOR to NHS Digital. Confirmation within section 5b of the application that the applicant will not link the data further and the only data linkages are those permitted under this application Confirmation within section 5 of the application that the individual accessing the data are substantive employees with the appropriate honorary contract in place which will include a clause that the substantive employer of the person under the honorary contract will take the appropriate action in the event of a breach. To update section 3b to confirm that the legal basis for dissemination of Civil Registration Data is the Health and Social Care Act 2012. 	OOC by IGARD Members	Quorum of IGARD Members	N/A
NIC- 150856- G6P5R	University of Warwick	02/08/2018	 Confirmation there is no flow of data from NHS Digital to ICNARC / NICOR and confirmation there is no flow of data from ICNARC / NICOR to NHS Digital. Confirmation within section 5b of the application that the applicant will not link the data further and the only data linkages are those permitted under this application Confirmation within section 5 of the application that the individual accessing the data are substantive employees with 	OOC by IGARD Members	Quorum of IGARD Members	 The following amendments be made within section 5: an amendment to section 5 as per the wording of the linked application. remove reference to honorary contracts

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

• None notified to IGARD