

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 16 November 2017

Members: Sarah Baalham, Joanne Bailey, Nicola Fear, Jon Fistein, Kirsty Irvine (Deputy Chair), Eve Sariyiannidou

In attendance: Arjun Dhillon, Jen Donald, Louise Dunn, Rachel Farrand, Frances Hancox, Dickie Langley, Kimberley Watson, Vicki Williams

Apologies: Chris Carrigan, Anomika Bedi

<p>1</p>	<p>Declaration of interests</p> <p>No relevant interests were declared.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 9 November 2017 IGARD meeting were reviewed and two typographical errors were noted. Otherwise the minutes were agreed as an accurate record of the meeting.</p> <p>Action updates were provided (see Appendix A).</p> <p>Out of committee recommendations</p> <p>An out of committee report was provided (see Appendix B).</p>
<p>2</p> <p>2.1</p>	<p>Data applications</p> <p><u>University of Oxford - Interactions between adipose tissue, vascular wall and myocardium in human atherosclerosis (Presenter: Jen Donald) NIC-392669-T1F8B</u></p> <p>Application: This was a new application to request linked Hospital Episode Statistics (HES) data, Office for National Statistics (ONS) mortality data and list cleaning for a cohort of consented study participants. It was noted that IGARD had previously reviewed the study consent materials on 25 May 2017 and that as a result the applicant had drafted a newsletter to help inform participants of the intended data processing and how they could withdraw consent. The applicant had also committed to update their study website with the details included in the newsletter.</p> <p>IGARD were notified of some omissions within the application as this did not currently list the ONS user details, and did not include clarifying information about the funding in place from the British Heart Foundation and the Biomedical Research Centre. It was noted that the application would be updated to include these details, and to list the correct subsection of the Health and Social Care Act 2012 under the legal basis for data dissemination.</p> <p>Discussion: IGARD queried a reference to European Commission funding and it was confirmed that this funding was no longer in place and not relevant to the current application.</p> <p>IGARD welcomed the fair processing efforts made by the applicant to provide and noted that it would be important to ensure that the study website was updated in a timely fashion as well as issuing the newsletter to participants. It was noted that the applicant intended to allow a period of time between sending the newsletter and receiving data, in order to provide time for any participants wishing to withdraw their consent to do so.</p>

The draft newsletter was discussed and IGARD suggested that both this and the consent materials should be updated to refer to data as pseudonymised rather than anonymised, as otherwise this could potentially be misleading.

IGARD queried whether the applicant had sought updated approval from a Research Ethics Committee, as it was noted that the ethics approval referred to version 6 of the protocol whereas the copy provided to IGARD was version 7.

A query was raised about a statement within the application that 'the results will not be used to directly establish a protocol for a clinical trial', as it was noted that any published outputs could in theory be used for this purpose by other research organisations. It was agreed this statement should be either clarified or removed. A further query was raised about the planned data retention period, as this was described inconsistently between the application and various supporting documents. In addition IGARD asked for section 5A of the application to be updated to more clearly explain the list cleaning that would take place prior to the planned linkage to ONS mortality data.

Outcome: Recommendation to approve, subject to:

- Confirmation of whether the applicant has sought updated ethics review based on the updated protocol, or whether the changes made were only considered minor amendments.

The following amendments were requested:

- The application would be updated to list the two funding organisations, correctly state the legal basis under the Health and Social Care Act 2012, and list all ONS user details.
- Section 5A should be amended to provide a clearer explanation of the list cleaning that will take place prior to the linkage to ONS mortality data.
- Section 5C should be amended to remove statement that results will not be used to establish a protocol for a clinical trial.
- The application should be updated to confirm the planned retention period.

The following advice was given:

- IGARD advised that the consent materials and newsletter wording should be updated to describe data as pseudonymised rather than anonymised.
- It was agreed the above condition would be reviewed out of committee by the IGARD Chair.

2.2

Regional Drug and Therapeutic Centre, Newcastle Upon Tyne Hospitals NHS Foundation Trust (Presenter: Rachel Farrand) NIC-135277-R8M3G

Application: This application requested access to pseudonymised HES data via the HES Data Interrogation System (HDIS). IGARD were informed that Newcastle Upon Tyne Hospitals had previously had access to HDIS but that this had been suspended following a data sharing breach. NHS Digital were content that appropriate progress had now been made following that breach and the submitted application was from a separate department within the Trust.

Discussion: There was a brief discussion of the level of data that would be provided in CCG reports; IGARD asked for the application to be updated to include a statement that any published reports would not contain data that would identify individual general practices. In addition it was agreed that the application should more clearly describe the reports that would be provided to CCGs.

IGARD queried whether the applicant currently held any record level HES data; it was confirmed that the applicant had provided a data destruction certificate for any data previously downloaded via HDIS, and that no extracts of HES data were held under separate agreement. IGARD also queried the need for national rather than regional data and it was agreed the application should provide a clearer explanation for this, noting the current technical limitations

of HDIS as the data available to the applicant could not be further filtered.

Outcome: Recommendation to approve.

The following amendments were requested:

- Section 5A should be updated to more clearly describe the reports that CCGs will receive.
- Section 5B should be amended to refer to the special conditions listed in section 6 as appropriate.
- The application should be updated to include a statement that any published outputs will not identify individual general practices.
- A clearer justification should be added of why the applicant requires national data.
- A statement should be added to the application that the applicant does not currently hold any record level extract of HES data provided by NHS Digital.

The following advice was given:

- IGARD advised that the applicant should update their DPA registration to refer to processing data about patients rather than 'our patients'.

2.3

Royal Devon and Exeter NHS Foundation Trust - MR766 Diabetes Alliance for Research in England (Presenter: Dickie Langley) NIC-147863-CCGZN

Application: This renewal application requested patient tracking services for a study cohort. It was noted that NHS Digital had confirmed that the different storage locations listed were all part of the Foundation Trust. IGARD were informed that although details of honorary contracts had been provided, only substantive employees of the Trust would process the data.

Discussion: IGARD noted that the legal basis to disseminate data was listed as section 261(7) of the Health and Social Care Act 2012 but that this should be corrected to section 261(2)(c) as this related to informed patient consent.

The consent materials were discussed and IGARD noted that although the historical materials had been imperfect, they were compatible with the proposed use of data and appropriate steps had been taken to update participants via fair processing materials.

IGARD briefly discussed the honorary contracts and noted that while the current application restricted data access to substantive employees only, if the applicant in future wished to change this then they would need to either update the honorary contracts or add an addendum in line with the standard NHS Digital requirements regarding honorary contracts.

A query was raised about the participant cohort and it was clarified that this included both the participants with diabetes and other participants without diabetes who had been recruited into the control group. IGARD asked for the application to be explained more clearly, as otherwise the application could be read to mean that only data about participants with diabetes would be provided under this agreement. In addition IGARD asked for the application to more clearly explain that although participants had been recruited nationwide, only data about participants from a particular region would be provided under this agreement.

IGARD noted that one of the supporting documents referred to approval by research ethics committee but that details of this approval had not been provided with the application. IGARD requested sight of the latest ethics approval letter and suggested that the application should be updated to include the approval details.

Outcome: Recommendation to approve, subject to condition:

- Providing a copy of the applicant's latest research ethics approval letter.

The following amendments were requested:

- The application should be updated to refer to section 261(2)(c) of the Health and Social Care Act 2012 as the relevant legal basis.

- Sections 3 and 5 of the application should be updated to clarify that references to 'study participants' includes both the cohort with diabetes and the control group.
- The application should more clearly explain that the data requested relates to participants recruited in the Exeter region rather than the full nationwide cohort.
- Section 5B should be amended to be clear that the use of ONS data is subject to ONS terms and conditions.

The following advice was given:

- If the applicant intends to use individuals working under honorary contracts to process this data in future, these contracts should be updated in line with NHS Digital's standard expectations.
- IGARD advised that the applicant should update their DPA registration to refer to processing data about research participants as well as 'our patients'.

It was agreed that the above condition would be considered out of committee by the IGARD Chair.

2.4

University of Sheffield - Collaborative European NeuroTrauma Effectiveness Research in Traumatic Brain Injury (Presenter: Dickie Langley) NIC-62448 -Z8K5T

Application: This application for pseudonymised HES data had previously been considered at the 31 August 2017 meeting, when IGARD had deferred making a recommendation. The application had been updated to include a clearer commitment from the applicant that data would not be shared, but had not provided a copy of the European Commission project proposal as they had indicated that this was a confidential document.

Discussion: IGARD strongly expressed their support for the aims of this study; however concerns were raised that the queries previously raised by IGARD had not been adequately addressed. In particular IGARD noted that the applicant was participating in the second stage of the project, which required the population of registries, and IGARD therefore requested clearer evidence that the applicant would not use data disseminated by NHS Digital for that purpose. It was suggested that the applicant might wish to consider permitting a senior member of NHS Digital staff sight of the project proposal if they did not consider it appropriate to share this more widely, although it was thought that these documents were not typically treated as confidential once a project had been agreed and was underway.

IGARD agreed to provide the presenter with a copy of a more recent IGARD paper relating to this type of application with EU funding and the typical expectations regarding aspects such as commercialisation and data sharing. It was agreed that the application should be updated to address the key points set out within that paper.

A query was raised regarding ethical approval and it was noted that the applicant had completed the HRA tool, which indicated that ethical approval was not required; it was thought that this was due to the use of pseudonymised rather than identifiable data.

Outcome: Recommendation deferred, pending:

- Providing appropriate evidence that the applicant will not use NHS Digital data to populate the registries they are responsible for creating under this European Commission funded project.
- Updating the application to address the criteria set out in the IGARD paper on this type of EU funded application.
- Section 5B should be amended to refer to the special conditions listed in section 6.

2.5

Monitor (Presenter: Louise Dunn) NIC-15814-C6W9R

Application: This was an amendment and renewal application from Monitor and the Trust Development Authority acting as data controllers in common, with the requested amendment

being the addition of Patient Level Information Costings (PLICs) mental health data. IGARD were informed that since the previous application version was reviewed in September 2017 the purpose section had been rewritten for clarity and to incorporate a number of earlier amendments into a more readable format, but that there had been no substantive changes to the purposes for which data would be used.

Discussion: IGARD acknowledged the significant work that had been undertaken to clarify the purpose section of this application and expressed their thanks.

It was noted that PLICS data was not currently listed in the tables of data requested and held; IGARD were informed that this was because PLICS was not a standard dataset that was available for request by other applicants but instead was part of a mandatory request. IGARD asked for this to be noted in the application abstract so that this would be clear for future versions of the application. In addition IGARD asked for the abstract to include a brief summary of the approvals history for this application as it was thought some relevant details were currently missing.

IGARD discussed the data requirements of the two organisations and noted that Monitor required access to PLICS data but that the Trust Development Authority did not intend to use this data. It was suggested that the list of data requirements for each organisation should be updated to be clear that Monitor would now have use of PLICS mental health data in addition to the original PLICS data.

IGARD queried a reference to HES CIP and it was explained that this described three additional fields that were not currently typically provided to applicants receiving HES data, but that this would likely be made available to other applicants in future. It was suggested that the description of outcomes using CIP should be updated to refer to the Single Oversight Framework in line with the references made to this in relation to other outputs.

Outcome: Recommendation to approve.

- The application should be amended to be clear that Monitor will now have access to Mental Health PLICS data in addition to the already held PLICS data.
- The description of example outputs using CIP referred to in section 5C should be updated to include reference to the Single Oversight Framework.
- The abstract should be amended to include a brief explanation of why PLICS data is not listed in the table of data requested.
- The abstract should also be amended to include a brief approvals history for this application.

The following advice was given:

- IGARD advised that Monitor and Advanced 365 should update their DPA registration to reflect processing data about patients or health service users.

3

Any other business

NIC-07289-G8J6C Northgate Public Services (UK) Ltd

IGARD noted that following the 9 November 2017 meeting, when IGARD had deferred making a recommendation on this application:

Outcome: Recommendation deferred, pending:

- Section five of the application must include a clearer explanation of why the applicant requires identifiable data for individuals have not consented, with this accurately reflecting the explanation provided for the applicant's section 251 support to ensure the full purpose is covered by the legal basis.

The following amendments were requested:

- The abstract should be updated to refer to the additional section 251 documentation

provided as evidence of legal basis.

- Confirmation that the application includes a statement that Isle of Man data will be sourced elsewhere.
- The processing activities section should be updated to clarify that the data previously provided to the applicant has been destroyed as this did not have patient objections applied, and therefore data will be resupplied with objections applied.

NHS Digital had taken the decision to approve the dissemination of data. The IGARD Chair had been informed of this out of committee. It was suggested that in future it would be helpful to also include the IGARD Deputy Chair in this type of communication.

Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
20/04/17	IGARD Chair to contact key stakeholder organisations regarding the benefits of uses of data to feed into the IGARD annual report.	IGARD Chair	14/09/17: Ongoing. It was agreed this would be discussed during the educational session. 05/10/17: It was agreed that the first draft would be discussed at December's education session. 16/11/17: Ongoing	Open
27/04/17	IGARD Chair to contact the NHS Digital Caldicott Guardian regarding GPs' data controller responsibilities for fair processing around risk stratification.	Arjun Dhillon	18/05/17: Ongoing. It was agreed this would be discussed with the Deputy Caldicott Guardian. 22/06/17: Ongoing; it was suggested the Deputy Caldicott Guardian should discuss this in more detail with Joanne Bailey. 29/06/17: It was noted this action would be taken forward by the Deputy Caldicott Guardian, and the action owner was updated. 20/07/17: It was agreed the Deputy Caldicott Guardian would provide an update on the current status of this. 10/08/17: An update from NHS England had been requested. 09/11/17: A response from NHS England had been received and this would be circulated to IGARD by email. 16/11/17: Ongoing	Open
18/05/17	Garry Coleman to provide information about different arrangements for data storage and backup locations, for consideration of whether the organisations involved would be considered to be processing data.	Garry Coleman	15/06/17: IGARD had been advised by email that a paper about this would be submitted to an upcoming IGARD meeting. 22/06/17: It was anticipated that this would be discussed at the 6 July 2017 IGARD meeting. IGARD asked for some information to be circulated by email prior to the meeting in order to inform members who would not be present at that particular meeting. 27/07/17: An email had been circulated requesting further information from IGARD members. 03/08/17: Two IGARD members had responded by email and the action remained ongoing. 10/08/17: It was anticipated that a paper on this would be brought to	Open

			<p>IGARD within the following two weeks.</p> <p>24/08/17: The paper was in the process of being updated based on recently published ICO guidance.</p> <p>14/09/17: Ongoing. IGARD noted that given the amount of time that had passed, they would consider starting to note this on relevant applications where a data storage location was not listed as a data processor.</p> <p>21/09/17: Ongoing. IGARD asked for Dickie Langley to provide an update on Garry Coleman's open actions at the next meeting to help ensure timely progression.</p> <p>02/11/17: IGARD discussed this action with Garry Coleman and requested a written update in response to the points previously raised by IGARD. Some difficulties were acknowledged as this specific scenario did not seem to be addressed in existing ICO guidance; IGARD suggested that NHS Digital should seek legal advice and if necessary then contact the ICO directly.</p> <p>16/11/17: Ongoing. IGARD queried the progress made regarding this action and there was a suggestion that this should be discussed at an education session; however it was suggested that it would be necessary to receive an updated response from NHS Digital before this.</p>	
20/07/17	Garry Coleman to provide an update within two weeks on how NHS Digital manage the risk involved in CCGs using South Central and West CSU as a data processor in light of data sharing breaches and recent audits.	Garry Coleman	<p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>24/08/17: IGARD received a verbal update on the work that had taken place following both audits and verbal assurances that NHS Digital were content with the level of risk involved in this organisation continuing to act as a data processor. IGARD welcomed this update and requested written confirmation.</p> <p>31/08/17: IGARD were notified that the requested written confirmation should be provided within one day.</p> <p>14/09/17: An email response had been circulated on 31 August, and IGARD noted that they were awaiting receipt of the post-audit report.</p> <p>16/11/17: Ongoing</p>	Open

20/07/17	Garry Coleman to categorise different standard lengths of indicative data retention periods for general research and clinical trials, with appropriate justification.	Garry Coleman	16/11/17: Ongoing	Open
31/08/17	Garry Coleman to report back on how cancer registration data was previously described as pseudonymised PDS data within older versions of applications, and present to a future education session on changes to how MRIS reports are now shown within applications.	Garry Coleman	16/11/17: Ongoing	Open
14/09/17	Stuart Richardson to provide IGARD with a copy of the Directions relating to the Emergency Care Data Set (ECDS) with confirmation of the date this was approved by the NHS Digital Board.	Stuart Richardson	21/09/17: The Directions had been provided by email. IGARD members were asked to provide any comments by email, ahead of potentially closing the action at the next meeting. It was noted that confirmation would still be required of NHS Digital Board approval. 16/11/17: Ongoing	Open
14/09/17	Stuart Richardson to provide IGARD with a copy of the Directions relating to Social Care Data with confirmation of the date this was approved by the NHS Digital Board.	Stuart Richardson	21/09/17: The Directions had been provided by email. IGARD members were asked to provide any comments by email, ahead of potentially closing the action at the next meeting. It was noted that confirmation would still be required of NHS Digital Board approval. 16/11/17: Ongoing	Open
21/09/17	Dickie Langley to provide a briefing paper (with relevant supporting documents) regarding the legal basis for receipt of data from Department for Education, and for this to be reviewed by the IG Advisor prior to circulation to IGARD.	Dickie Langley	16/11/17: Ongoing	Open
21/09/17	Dickie Langley to provide IGARD with a copy of the new standard DSA terms and conditions.	Dickie Langley	16/11/17: Ongoing	Open
19/10/17	Stuart Richardson to provide a briefing on the Temporary National Repository infrastructure.	Stuart Richardson	16/11/17: Ongoing	Open
02/11/17	NHS Digital to consider the responses provided by an applicant (Imperial College London NIC-27085) in		16/11/17: Ongoing	Open

	relation to the language and terminology used in patient information materials.			
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Appendix B: Out of committee report (as of 10/11/17)

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-302792	University of Warwick	28/09/17	<ul style="list-style-type: none"> Providing evidence that NHS Digital is content that the fair processing information published on the study website meets the nine minimum criteria for privacy notices. IGARD advised that the study website should be updated to remove references to data about deaths as this was not currently provided, and should also provide contact details for individuals wishing to opt out. 	IGARD Members	IGARD Quorum	N/A

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

- None