

# Independent Group Advising on the Release of Data (IGARD)

## Minutes of meeting held 27 July 2017

**Members:** Sarah Baalham, Joanne Bailey, Anomika Bedi, Chris Carrigan, Jon Fistein, Kirsty Irvine

**In attendance:** Rachel Farrand (observer), Frances Hancox, Louise Hill, James Humphries-Hart, Dickie Langley, Vicki Williams

**Apologies:** Nicola Fear, Eve Sariyiannidou, James Wilson

<p>1</p>	<p><b>Declaration of interests</b></p> <p>Jon Fistein noted a potential interest in the University of Cambridge application (NIC-302473-K6R0Z) due to a working relationship with one of the study co-investigators but it was agreed this should not prevent his participation in the discussion of that item.</p> <p>Chris Carrigan noted a potential interest in the Royal College of Surgeons application (NIC-15335-H0D1F) due to involvement with similar cancer audit work carried out by the University of Leeds, but it was agreed this did not represent a substantive conflict of interests.</p> <p><b>Review of previous minutes and actions</b></p> <p>The minutes of the 20 July 2017 IGARD meeting were reviewed and a minor change to the Any Other Business discussion was agreed. The IGARD Chair noted an error in how the IMS Health Ltd application (NIC-13925-Q7R2D) had been recorded in the out of committee report and it was agreed this would be corrected. Subject to these changes the minutes were agreed as an accurate record of the meeting.</p> <p>Action updates were provided (see Appendix A).</p> <p><b>Out of committee recommendations</b></p> <p>An out of committee report was provided (see Appendix B). A minor change to the report was suggested.</p>
<p>2</p> <p>2.1</p>	<p><b>Data applications</b></p> <p><u>University of Cambridge - Epidemiological Study of BRCA1 and BRCA2 Mutation Carriers (Presenter: Dickie Langley) NIC-302473-K6R0Z</u></p> <p><b>Application:</b> This application was to retain Personal Demographics Service (PDS) data, Cancer Registration data and Office for National Statistics (ONS) mortality data previously provided by NHS Digital's Medical Research Information Service (MRIS) for a specific cohort of individuals. IGARD were notified that as the applicant's previous agreement had expired, they had been required to submit an appropriate renewal application by the end of July 2017 or otherwise destroy the data held.</p> <p><b>Discussion:</b> IGARD queried the legal basis under the applicant's section 251 support as the documentation provided stated that this only applied to the 'retrospective cohort' as defined in June 2015. On that basis it was agreed that the application would need to be updated to make clear that data would only be provided for the retrospective cohort as agreed with HRA CAG, as no information was provided about the legal basis for any participants recruited more recently.</p>

Confirmation was requested of whether the study's Research Ethics Committee (REC) approval had been renewed as the documentation provided seemed to indicate that approval was only in place until January 2017.

IGARD noted that a short term agreement was requested that would run until the end of September 2017. It was agreed that the renewal application would need to include more information about the applicant's fair processing efforts and how their privacy notice had been updated in order to meet NHS Digital's nine minimum criteria. IGARD also suggested that the renewal application should include more information about the outputs and benefits that had been achieved or were anticipated.

A query was raised about data sharing with other organisations, as it was noted that the study protocol referred to an international collaborator and a researcher based at a hospital in Leeds. It was confirmed that this application would not permit data sharing with any third party organisations and that any references to data sharing within the protocol did not relate to data received from NHS Digital.

Concerns were raised about the consent materials provided, particular as recruitment appeared to be ongoing and the section 251 support did not seem to provide a legal basis for a prospective cohort. IGARD were informed that the current application was only for the cohort covered by the section 251 support and that due to the differing legal bases, any renewal request including a consented cohort would need to be submitted as two separate applications with one application covering the retrospective, section 251 cohort and the other application covering the prospective, consented cohort. It was agreed that the application relating to the prospective cohort would need to contain more information about the legal basis under consent and what efforts had been made to improve the materials made available to participants.

There was a discussion of the information typically provided alongside applications about funding arrangements, and what level of detail might be appropriate for different types of funding arrangements. It was agreed that the Deputy Caldicott Guardian would consider this point further and report back to IGARD. For this particular application it was agreed that a statement should be added to section five that the funding organisation cannot influence the outputs of the research or restrict their dissemination

IGARD asked for section nine of the application to be updated to include details of the study's Microdata Release Panel approval to use ONS data in addition to the Approved Researcher details currently shown. However it was noted that the Microdata Release Panel information was already recorded elsewhere in the application. IGARD suggested that NHS Digital should consider how details of ONS approvals should be consistently recorded in applications to help minimise the risk that information about one of the two types of approvals could be overlooked. In addition it was agreed that section five of the application should be amended to include a statement that ONS data would be handled in accordance with ONS terms and conditions, as well as reflecting any other relevant special conditions.

**Outcome:** Recommendation to approve for the retrospective cohort only as supported by HRA CAG, subject to:

- Providing evidence of renewed REC approval as the documentation provided appeared to have expired in January 2017.

The application should be updated to state that the funding organisation cannot influence the outputs of the research or restrict their dissemination. The application should be updated to confirm that data will only be provided for the retrospective cohort as defined by the applicant's section 251 support.

Section five of the application should be amended to reflect the relevant special conditions. It was noted that the renewal application would need to include details of how the applicant's fair processing had been updated in order to meet NHS Digital's nine point check.

It was the view of IGARD that the updated application would not be appropriate for renewal by IAO and Director delegated authority. IGARD suggested that NHS Digital might wish to consider carrying out a data sharing audit of this applicant.

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

**Action:** Arjun Dhillon to provide information for IGARD about the robustness of different funding processes and how this might affect the level of scrutiny applied to or information included in applications provided to IGARD.

## 2.2

### Royal College of Surgeons (Presenter: Dickie Langley) NIC-15335-H0D1F

**Application:** This application requested the extension and renewal of a previous agreement for Hospital Episode Statistics (HES) and ONS mortality data including the identifiable field date of death, as well as amending the agreement to remove one of the previous projects (FFAP Fragility Fracture). Data would continue to be used for a number of different listed projects and it was noted the application indicated which of these projects would use ONS data. IGARD were informed that the HES maternity data would contain baby date of birth, but that this was not considered an identifier in relation to the mother's records.

An error in the application was noted as the legal basis listed in section three did not cite the correct sub-section of the Health and Social Care Act 2012. It was noted that the application included special condition requiring the applicant to provide details of the outputs and benefits achieved or expected as a result for each individual project ahead of any future request to extend or renew the agreement. In addition it was noted that the applicant should update their DPA registration wording to cover processing data about patients.

**Discussion:** IGARD queried the list of ONS data users, as the application appeared to state that some of these users only worked on projects that were not listed as requiring ONS data. It was agreed the ONS user list should be updated to only include those users who would be working on projects requiring ONS mortality data.

IGARD noted the involvement of the involvement of C Hoare & Co in this application as a backup storage location and suggested that NHS Digital should consider this in light of the currently open action regarding data storage locations. More broadly IGARD noted that the backup storage process described seemed somewhat unusual and suggested NHS Digital should assure itself that it was content with the security arrangements in place.

There was a discussion of the legal basis for ONS data to be disseminated under section 42(4) of the Statistics and Registration Service Act 2007, and it was clarified that this was applicable due to this work being commissioned by HQIP on behalf of NHS England. It was confirmed that an appropriate commissioning letter was in place for this use of data. However a query was raised about data disseminated by NHS Digital under separate agreements for clinical audits commissioned by HQIP, and whether this potentially duplicated the data requested for clinical audits within this application. IGARD suggested that NHS Digital should consider the other data sharing agreements currently in place to share data for clinical audits commissioned by HQIP and ensure there was no inappropriate duplication of data sharing.

There was a brief discussion of the formatting of this application and the difficulties raised by considering several purposes within a single application; IGARD suggested that in future NHS Digital might wish to work with the application to consider splitting this application into multiple separate agreements. In addition IGARD noted the description in section five of the application of how the Director of the CEU would approve the use of data for specific purposes and suggested that in future it would be helpful to explain this arrangement more clearly in a way that would be accessible to the general public.

A query was raised about the years of ONS data requested, as this included data from 2000

onwards but the list of data required for each project seemed to indicate that only data from 2002 onwards would be needed. It was agreed the application should be updated to remove the request for ONS data from 2000 – 2002 and to confirm that this data would be securely destroyed.

IGARD queried the description of current funding arrangements and suggested the application should be amended to confirm that funding is ongoing. It was noted that the Director of the CEU had committed to publish an appropriately updated privacy notice ahead of any subsequent applications and IGARD asked for a special condition to be added to the application to reflect this commitment. The potential benefits of this work were discussed and IGARD suggested that the applicant should consider disseminating the outputs of each project more widely to help maximise the potential benefits to healthcare. A typographical error in section five was noted. It was agreed section five should be updated to include the standard wording requiring the applicant to not attempt to re-identify individuals from the data and restricting linkage to other record level data.

**Outcome:** Recommendation to approve.

The application should be amended to update the list of ONS users to remove any users not working on a project that will make use of ONS data. The application should also be amended to confirm that funding is ongoing. The table of data requested should be amended to remove ONS data from 2000 – 2002 and to confirm that this will be destroyed.

The legal basis should be amended to state section 261(7) of the Health and Social Care Act 2012 instead of section 261(1). A special condition should be added to the application that the applicant will work with NHS Digital to consider how these multiple projects might best be reflected across separate applications. A special condition should also be added that an appropriate privacy notice must be published ahead of the next application. Section five should be amended to include the standard requirement that the applicant will not attempt to re-identify data and will not link to any other record level data.

IGARD advised that NHS Digital should ensure that the data flows requested under this application for clinical audits are not duplicating existing data flows from NHS Digital for the same clinical audits. In addition IGARD advised that the applicant should consider how they could disseminate the outputs of this work more widely and in a more transparent way to help ensure benefits. IGARD advised that NHS Digital should ensure they are content regarding the security of backup storage arrangements described in this application. The applicant should update their DPA registration to include processing data about patients or health service users.

IGARD noted that there was currently an open action with NHS Digital regarding data storage and backup locations and how their data processing role was reflected in applications and suggested that NHS Digital should consider the involvement of C Hoare & Co in this application in light of that action.

### 2.3

Islington CCG (Presenter: James Humphries-Hart) NIC-99094-L3H5G

**Application:** This application requested pseudonymised Secondary Uses Service (SUS), local flows, mental health (MHMDS, MHLDDS, MHSDS), Improving Access to Psychological Therapies (IAPT), maternity (MSDS), Children and Young People's Health (CYPHs), and Diagnostic Imaging Dataset (DIDs) data for the purpose of commissioning, with MedeAnalytics acting as data processor and North East London CSU acting as a landing stage only. The data would be pseudonymised within the DSCRO using the MedeAnalytics pseudonymisation tool, enabling linkage with pseudonymised at source data received into MedeAnalytics from a variety of sources including social care data and GP data. IGARD were informed that the CCG's privacy notice had been assessed as passing NHS Digital's nine point check, and an error was noted in the time period of data requested as this should be until 30 June 2018 in line with the proposed agreement end date.

**Discussion:** IGARD welcomed the information provided about the CCG's privacy notice and

advised that the CCG should update this to reflect the new involvement of MedeAnalytics.

It was noted that the special condition wording relating to privacy notices should be updated to the current standard advice wording. IGARD asked for a statement in the application about only 'MedeAnalytics operational staff' having access to data to be amended to specify that this would only include staff with employment contracts. A query was raised about the special condition wording relating to Interxion but it was thought that this was standard wording. A further query was raised about the special condition relating to data destruction as it was noted that the applicant would continue to retain the data provided under separate data sharing agreements, and IGARD suggested the special condition wording should be updated to only relate to destruction of identifiable data held for the same purpose as set out within this current application.

There was a discussion about the relevant legal basis for dissemination under the Health and Social Care Act 2012 and which sub-sections would be applicable. It was agreed the application should be amended to specifically state that the applicant would not attempt to re-identify individuals from the data providing (as re-identification would only be permitted by GPs with a legitimate relationship for direct care purposes). In addition it was agreed that the current application wording that GPs would only be able to reidentify patients 'when they have a legitimate reason and a legal right' should be amended to refer to the legitimate relationship between a GP and a patient.

**Outcome:** Recommendation to approve.

The special condition wording around destruction of identifiable data previously held should be amended to reflect that this refers to data held for the purposes of this application.

A reference to data access being restricted to MedeAnalytics operational staff should be amended to be clear this refers to staff with employment contracts. A statement that GPs will re-identify patients "only when they have a legitimate reason and a legal right to re-identify" should be amended to instead refer to having a legitimate relationship with the patient. A statement that no record level data will be linked other than as specifically detailed within the application should be amended to include that there will be no attempt to re-identify the data other than as described for a GP with a legitimate relationship with the patient.

IGARD noted that the applicant's privacy notice would need to be updated to reflect the involvement of MedeAnalytics as a data processor.

2.4

Cambridgeshire and Peterborough CCG (Presenter: James Humphries-Hart) NIC-95040-Y0P3W

**Application:** This application requested pseudonymised SUS, local flows, mental health (MHMDS, MHLDDS, MHSDS), MSDS, IAPT, CYPHs and DIDs data for the purpose of commissioning with North of England CSU acting as data processor. IGARD were informed that the CCG's privacy notice had not passed NHS Digital's nine point check.

**Discussion:** IGARD discussed the CCG's privacy notice and one IGARD member noted that trying to access the privacy notice had resulted in an error message; IGARD emphasised the importance of ensuring that the notice would be easily accessible to the general public. A query was raised about the definitions of data used in the privacy notice and it was agreed the CCG should ensure these were in line with current best practice terminology.

**Outcome:** Recommendation to approve, subject to:

- The CCG should update their privacy notice in line with NHS Digital's nine criteria and in particular should ensure that it is easily accessible on the website, describes who data is shared with and ensure that definitions such as 'anonymised' data are in line with best practice terminology.

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

<b>3</b>	<b>Any other business</b> No other business was raised.
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## Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
15/11/16	To update DAAG on the feasibility of providing random samples of data to applicants, and to ask the Production Team to provide DAAG with further information about the options for data minimisation	Garry Coleman	<p>06/12/16: This action was ongoing and it was anticipated an update would be available in mid-January. There had also been a discussion during the training session about data minimisation, with a suggestion for Peter Short to contact the Production Team for further information, and it was agreed that would be incorporated into this action.</p> <p>20/12/16: It was anticipated an update would be available in mid-January.</p> <p>10/01/17: Ongoing. It was agreed that this action would be taken forward by Alan Hassey rather than Peter Short.</p> <p>17/01/17: A number of internal discussions had taken place and it was anticipated an update would be brought to DAAG within the next few weeks.</p> <p>31/01/17: Ongoing. It was agreed the IGARD Chair would request an update on progress of this action.</p> <p>09/03/17: Ongoing. A number of internal discussions continued to take place and it was agreed the action would be taken forward by Garry Colman.</p> <p>23/03/17: Ongoing. There was a suggestion it might be helpful to discuss the type of sampling used by the Department for Work and Pensions.</p> <p>11/05/17: This action was not discussed due to time restrictions.</p> <p>18/05/17: IGARD received a verbal update on work underway to develop 'dummy data' for the purpose of developing tools and algorithms.</p> <p>15/06/17: It was agreed the IGARD Chair would contact Garry Coleman about this action and ask whether an update could be provided in the near future, or if not then agree to close the action</p>	Open

			and to raise the topic again at a later date. 27/07/17: Ongoing.	
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	27/07/17: 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. 27/07/17: 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.	Open
15/06/17	Data Services for Commissioners to work with NHS Digital IG staff to check the privacy notices for these 4 CCGs (South Kent Coast CCG; Ashford CCG; Thanet CCG; Canterbury & Coastal CCG) as part of the ongoing training, and provide a copy of the outcome of this check to IGARD for information.	Stuart Richardson	29/06/17: Ongoing. It was suggested it would be helpful to discuss this at an upcoming educational session. 27/07/17: Ongoing.	Open
22/06/17	NHS Digital to ensure that in future applications using the Health and Social Care Act 2012 as a legal basis provide more detail about the applicable subsections, such as section 261(2)(b)(ii).	Garry Coleman	27/07/17: Ongoing.	Open

29/06/17	Stuart Richardson to contact DARS regarding standard data destruction timescales and processes where data processing is moving from one data processor to another.	Stuart Richardson	27/07/17: Ongoing.	Open
06/07/17	Stuart Richardson to circulate a suggested change to the updated 'substantive employees' wording for discussion out of committee.	Stuart Richardson	13/07/17: This proposed change had been circulated by email and IGARD members were asked to respond. 27/07/17: Ongoing.	Open
06/07/17	Stuart Richardson to ensure that privacy notice checklists are provided for all DSfC applications for a trial period of three months from 13 July IGARD meeting.	Stuart Richardson	27/07/17: Ongoing.	Open
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	27/07/17: Ongoing.	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	27/07/17: Ongoing.	Open
27/07/17	Arjun Dhillon to provide information for IGARD about the robustness of different funding processes and how this might affect the level of scrutiny applied to or information included in applications provided to IGARD.	Arjun Dhillon		Open

**Appendix B: Out of committee report (as of 21/07/17)**

These applications were previously recommended for approval with conditions by IGARD, and the conditions have subsequently 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 update application by:	Notes of out of committee review (inc. any changes)
NIC-24629-X6B6N	IMS Health Ltd	22/06/2017	<ul style="list-style-type: none"> <li>Providing the relevant appendices or earlier sub license document referred to within the amendment sub license.</li> </ul>	IGARD quorum	IGARD quorum	N/A
NIC-74625-S1Q8X	Cardiff University	13/07/17	<ul style="list-style-type: none"> <li>Confirmation of whether sex is considered an identifier, and if so whether sending this data item to NHS Digital is covered by section 251 support.</li> <li>Confirmation that the University of Bristol and the University of Oxford are not involved in this application as data processors.</li> </ul>	IGARD quorum	IGARD quorum	N/A

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

- NIC-15625-T8K6L CPRD
- NIC-147756-SMGHS Nuvia Ltd
- NIC-14340-R7G1F Beacon Consulting Ltd