Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 14 September 2017

Members: Joanne Bailey, Chris Carrigan (Chair), Nicola Fear, Jon Fistein, Kirsty Irvine, Eve Sariyiannidou

In attendance: Arjun Dhillon, Louise Dunn, Dan Goodwin (observer), Frances Hancox, Russell Heep (observer), James Humphries-Hart, Dickie Langley, Neil Lawrence (observer), Stuart Richardson, Vicki Williams

Apologies: Sarah Baalham, Anomika Bedi

1 Declaration of interests

Both Jon Fistein and Chris Carrigan declared a conflict of interests in relation to NIC-49164-R3G5K University of Leeds due to their work with the University of Leeds and professional relationships with the particular applicants. It was agreed they would leave the meeting for the discussion of that application, and that agenda item would be chaired by Kirsty Irvine.

Review of previous minutes and actions

The minutes of the 31 August 2017 IGARD meeting were reviewed and agreed as an accurate record of the meeting.

Action updates were provided (see Appendix A).

Out of committee recommendations

An out of committee report was provided (see Appendix B).

2 Data applications

2.1 <u>University Hospitals Birmingham NHS Foundation Trust – Benchmarking service (Presenter: Louise Dunn) NIC-06605-X1L9Z</u>

Application: This application requested an amendment to an existing data sharing agreement, to add Carnall Farrar as a subscriber organisation for the Healthcare Evaluation Data (HED) tool. It was noted that the existing data sharing agreement was due to expire in November and that a renewal application would be submitted to IGARD separately, so this application would not extend the existing agreement. In addition it was noted that the existing data sharing agreement stated that if the applicant wished to add any non-NHS organisations as subscribers for the HED tool, this would need to be subject to a request to NHS Digital; at present the only other non-NHS subscriber was PriceWaterhouse Coopers (PwC).

IGARD were informed that section three of the application would be updated to include the legal basis under section 251.

Discussion: IGARD noted that the application stated Carnall Farrar would only have sight of aggregated outputs with small numbers suppressed, and acknowledged that the existing agreement required the applicant to submit a request to add non-NHS organisations as subscribers to the tool even if these organisations would not have sight of record level data.

IGARD queried the approvals history for this application and what the IAO and Director approval had covered, as this was not clearly explained within the abstract. It was explained

that the IAO and Director approval had been due to an updated commissioning letter, which had provided a legal basis for ONS mortality data to be used for a wider subscriber base rather than solely for NHS subscriber. IGARD asked for the application to be updated with a clearer explanation of the timeline of approvals and what had been covered by previous DAAG approvals and the IAO and Director approval.

IGARD queried a statement within the application that for the East Midlands Academic Health Science Network (AHSN) the 'legal basis is under Nottingham University Hospitals NHS Trust' and it was agreed this should be clarified.

There was a brief discussion of the section 251 support for this data flow, as it was noted that the supporting letter provided was from summer 2016. It was confirmed that the applicant had submitted their renewal application to HRA CAG and that the CAG register had been updated to indicate that their section 251 support had been extended for another year, but that no further evidence of renewal was available from CAG. IGARD asked for the Approval Considerations section of the application to be updated to include an explanatory note about the renewal evidence provided.

IGARD queried a special condition relating to completing a 'CAG action plan' by October 2017 and were informed that the applicant had submitted evidence of completing this as part of their recent section 251 renewal. It was suggested the special condition wording should be either updated or removed.

IGARD noted a potential error in section five as at one point this referred to a non-NHS organisation 'i.e. PwC' holding a subscription, and suggested this wording should be amended to 'e.g. PwC' to allow for the fact that this would no longer be the only non-NHS subscriber. In addition it was noted that section three of the application should be updated to include the relevant sub-section of the Health and Social Care Act 2012 under the legal basis.

IGARD discussed the fair processing information provided by University Hospitals Birmingham, and noted that while this described how individuals could opt out this description was underneath the heading 'your right to withdraw consent'. IGARD considered that the reference to consent could be confusing or misleading, as this data flow did not rely on consent, and suggested that the applicant should update this wording. In addition it was noted that the privacy notice linked to within the application stated referred to possible consequences including 'delays in receiving care' and IGARD suggested that this wording should be amended to be clear that this only related to opting out of data sharing for direct care rather than secondary uses of data.

IGARD noted that some wording in section five of the application around adding 'one further non-NHS organisation' could be misleading, as the addition of Carnall Farrar had already been described earlier in the application; it was agreed this wording should be clarified or removed.

A query was raised about a previous special condition relating to data destruction and whether this had been completed; IGARD were informed that a data destruction certificate had been provided for the relevant data, and that as no new data would be disseminated under this application the same special condition would not be applicable to this agreement.

Outcome: Recommendation to approve.

The following amendments were requested:

- A clearer explanation should be provided of the chronology and approval history of this
 application and what was covered by the previous IAO and Director approval.
- A reference to East Midlands AHSN having a 'legal basis under Nottingham Hospital Trust' should be clarified.
- The applicant should commit to update their privacy notice to correct potentially misleading references to 'your right to withdraw consent' to instead refer to opting out, and to be clear if any other references to withdrawing consent are only relevant to the

use of data for direct care.

- A reference in section five to 'adding one further non-NHS organisation into the agreement' should be updated or removed for clarity.
- The approval considerations section of the application should be updated to include a short explanation about the section 251 renewal evidence provided.
- A special condition about to the action plan from HRA CAG needing to be completed by October 2017 should be updated.
- A reference to PwC within section five should be corrected to 'e.g. PwC'
- IGARD noted that section three would be amended to reflect the legal basis under section 251, and to list the full legal basis under the Health and Social Care Act 2012.

2.2 <u>University of Nottingham - Helicobacter Eradication Aspirin Trial HEAT (Presenter: Louise Dunn) NIC-389320-R4M6Z</u>

Application: This application requested an amendment to an existing data sharing agreement, with the amendment being to add TCR (Nottingham) Ltd as a data processor. It was noted this organisation had previously provided hosting and been listed within the agreement as a storage location, but that employees of the organisation would now be providing technical support that would enable them to have access to the data provided by NHS Digital.

Discussion: IGARD noted that the study did not have a patient-facing website, and that all communication with participants seemed to be via the annual newsletter. IGARD queried what steps had been taken to ensure that the study held up to date address details for participants, as otherwise it was possible that some participants would have been lost to follow-up and would not have received the newsletter updates containing information about the proposed uses of data. It was suggested that the applicant should consider undertaking a list cleaning exercise to ensure that up to date address information was held for all participants, and that the applicant should also strongly consider establishing a patient-facing website where individuals could find information about the study rather than being solely reliant on receiving the annual newsletter. IGARD noted that if a list cleaning exercise was undertaken then the applicant should ensure to inform participants of this, and that it would be helpful to consider undertaking list cleaning on a regular basis. It was suggested that the consent materials provided did not exclude the use of data for list cleaning.

The consent materials were discussed and IGARD suggested that when the study next undertook a scheduled update of these, they should consider adding a statement that the decision to withdraw consent would not affect an individual's care. It was also suggested that it would be helpful to update the materials at the same time to explain any planned list cleaning and the involvement of a data processor.

There was a discussion about the involvement of TCR (Nottingham) Ltd staff and whether these would be expected to fall under the description of 'trained members of the research team' as per the description given in a supporting document. It was suggested that the consent materials did not exclude this use of data as participants might reasonably expect that 'the research team' could include employees from different organisations, rather than solely University of Nottingham staff.

IGARD queried the wording of a statement within the application that the trial would not 'directly link' GP and Hospital Episode Statistics (HES) data, but that data would be compared at an individual patient level. It was noted that this use of data would be covered by consent but IGARD suggested it would be helpful to amend the description within the application for clarity. A reference within the application to 'our patient and public involvement group' was queried and IGARD asked for this to be updated to be clear this referred to a group hosted by the study, rather than an NHS Digital group. It was noted that within the list of ONS users, some rows listed the legal basis but some did not and IGARD asked for this to be amended for

consistency.

Outcome: Recommendation to approve, subject to:

Confirmation of whether the applicant will be undertaking list cleaning to ensure they
have up to date address details for all participants being sent a newsletter, or what
other steps have been taken to ensure address details are up to date. If list cleaning
has not been undertaken then the applicant should commit to carry this out within three
months. If list cleaning is undertaken, information about this should be included in the
upcoming newsletter and on a study website.

The following amendments were requested:

- The newsletter update to participants should include a clear explanation that a member of staff from TCR Nottingham will have access to data including ONS mortality data.
- A reference in the application to 'our patient and public involvement group' should be amended to be clear this is a group for the study rather than for NHS Digital.
- The list of ONS users should be updated to consistently list the legal basis.

The following advice was given:

- IGARD advised that the applicant should develop a patient facing website for the study.
- IGARD advised that when the study consent materials were next updated, the
 applicant should add a statement that withdrawing consent would not affect the care
 received by an individual, and to cover the use of data by a data processor as well as
 list cleaning.
- IGARD advised that the applicant should undertake regular list-cleaning of patient address details and inform participants of this.

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

2.3 Royal College of Anaesthetists - Perioperative Quality Improvement Programme PQIP (Presenter: Louise Dunn) NIC-63347-R8J2M

Application: This was a new application requesting pseudonymised HES data linked to ONS mortality data including the identifier Date of Death, based on patient consent for the data flow. It was noted that NHS Digital had provided advice on the study consent materials and that an updated version of the materials had been produced, which would be used for ongoing recruitment. IGARD were informed that the applicant's fair processing information had passed the NHS Digital nine point check and was now live on the website.

Discussion: IGARD agreed that the updated consent materials seemed to provide an appropriate legal basis in consent for the proposed data flows. However concerns were raised about the participants who had consented using the old version consent materials, as it was unclear what corrective actions the applicant had undertaken with regard to these individuals. IGARD requested more information about the number of participants who had consented using the old version and what steps had been taken to appropriately update them.

IGARD queried the descriptions of the first and second linkage, and how these related to the described linkage of Welsh and Scottish data. It was explained that the use of data from Wales and Scotland was separate to the data linkage described in this application and IGARD asked for the application to be updated to explain this and to state that NHS Digital data would not be disseminated to Wales or Scotland for this purpose. In addition it was agreed that references to sending identifiers should be amended to be clear which linkage this referred to.

IGARD suggested that the Royal College of Anaesthetists and University College London should both update their DPA registrations to ensure they covered the use of patient data for research purposes.

A query was raised about the cohort sizes described in section three of the application, as these seemed inconsistent, and it was agreed this should be corrected or clarified. The planned data retention period was queried and it was confirmed this should be corrected to

state that data would be retained until 2021, rather than 2051. In addition it was agreed that the description of the data as 'anonymised' within the application should be updated to instead state that the data would be pseudonymised.

Outcome: Recommendation to approve data sharing for participants who consented using the new consent materials (version one dated June 2017) only.

Recommendation deferred for participants who consented using the old consent materials (October 2016), pending:

Confirmation of what corrective action the applicant has taken to update participants
who consented using the old version of consent materials, including confirmation of
what number of participants have consented using the old version versus the updated
version.

The following amendments were requested:

- References to data linkage for Wales and Scotland should be amended for clarity and include a statement that NHS Digital data will not be disseminated to Wales or Scotland for the purpose of that linkage.
- References to sending identifiers to NHS Digital should be amended to be clear this
 only applies to the first linkage, and the descriptions of the first and second linkage
 should be more clearly separated.
- Descriptions of the data as anonymised should be amended to instead state that the data is pseudonymised.
- The cohort sizes should be clarified within section three.
- The data retention period should be corrected from 2051 to 2021.

The following advice was given:

• The Royal College of Anaesthetists should update their DPA registration to include the use of data for research, and UCL should update their DPA registration to refer to data about patients more broadly rather than 'our patients'.

2.4 University of Leeds - QuantiCode (Presenter: Dickie Langley) NIC-49164-R3G5K

Application: This was a new application requesting pseudonymised HES data for a research project related to developing data mining and visualization tools/techniques with large and complex datasets.

Discussion: IGARD queried the health or social care benefits that would be expected from this use of data, as while it was acknowledged that some benefits to NHS Digital could be expected it was agreed that the application did not provide a sufficiently clear explanation of what health or social care benefits could be expected in line with the requirements of the Care Act 2014. It was noted that the application was not written in a way that would be easily accessible to a lay audience, and it was agreed that section five should more clearly explain the restrictions on the purposes for which data could be used.

A clearer explanation was requested of how the data would be used for the benefit of health, and whether it would also be used for any other non-health benefits such as commercial uses. IGARD queried the statement within the application that this was not a commercial use of data and suggested that the explanation given in the abstract, which relating to using data to provide a proof of concept for a health-related tool, should be incorporated into the statement in section five that the purpose of this application was not in any way commercial. References to 'data fusion' were queried and IGARD asked how this could be reconciled with the commitment that data from other sources would be kept separate from the data provided by NHS Digital.

IGARD queried the amount of data requested and asked for a clearer justification for this to be included in the application. In addition IGARD asked for the application to be updated to more clearly state which uses of data had been completed and which were ongoing. The

involvement of the University of York as a data storage location was noted and IGARD queried whether this organisation should be considered a data processor. IGARD also queried the role of the project partners and requested more information about the collaboration agreement between the organisations.

IGARD suggested that the applicant should consider undertaking a Privacy Impact Assessment for this use of data.

Outcome: Recommendation deferred, pending:

- Clarification of how NHS Digital data will be used for the purpose of providing benefit to the NHS and how it will be used for any purposes not related to health or social care.
- Section five of the application should be updated to more clearly set out the restrictions on the purpose(s) for which the data can be used
- The statement that this use of data is not commercial should be updated to include the information provided in the abstract about the use of data to test a tool.
- Providing a clearer explanation of the expected benefits to healthcare.
- The application should more clearly explain what aspects of this work are ongoing or have already been completed.
- Providing more information about the collaboration agreement between the different organisations, and updating section five to include more information about the role of the partner organisations.
- A clearer explanation was requested about data minimisation and why it would not be sufficient to use a smaller amount of data for this purpose.
- Providing an explanation of whether the University of York should be considered a data processor, given their role in providing data storage.

The following advice was given:

- IGARD advised the applicant should review their website against the ICO's Privacy Notices Code of Practice to ensure they reflect best practice standards, and in the interests of transparency, update their privacy notice as soon as possible. The EU General Data Protection Regulation recognises that pseudonymised data should be considered as information on an identifiable natural person and also places a greater focus on the need to demonstrate transparency of data processing in the information provided to data subjects.
- IGARD advised that the applicant should undertake a Privacy Impact Assessment for this use of data.

2.5 Briefing paper: Emergency Care Data Set

IGARD were notified that NHS England had issued a Direction to support the collection of the Emergency Care Data Set (ECDS), which would gradually replace the A&E Commissioning Data Set. It was noted that where an applicant had approval to receive the A&E data set and this data ceased to be available, NHS Digital had taken the decision to instead supply these applicants with ECDS restricted to the current A&E data structures, so that no additional fields would be provided. At some point in the near future a class action application would be brought to IGARD to request for all CCGs to receive the full ECDS data. It was noted that the collection of this data had been reviewed by the Standardisation Committee for Care Information (SCCI).

IGARD requested further information about the specific Directions relating to this collection of data, and confirmation of what date the Direction had been agreed by the NHS Digital board. It was agreed this information would be required ahead of considering a class action application. In addition IGARD asked for the future application to include a clearer explanation of how the new ECDS differed from the old A&E data, such as what new fields or additional sensitivity would be included. IGARD also noted that any future applications requested ECDS data should be clear whether this referred to the full dataset, or to the restricted dataset shared under existing approvals for A&E data.

A query was raised about the increased richness of this data set and what steps NHS Digital would be taking to review the potentially increased risk of re-identification when this data was linked to a variety of other data, such as whether a Privacy Impact Assessment would be undertaken. IGARD received a brief verbal update on work underway to quantify the level of risk associated with different types of data disseminations.

Action: 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.

2.6 Briefing paper: Social Care data

IGARD were informed of a Direction to collect adult social care data from certain Local Authorities (Liverpool, Manchester and Rochdale) as part of an initial pilot, with this social care data being shared with NHS Digital's North West Data Services for Commissioners Regional Office (DSCRO) for linkage with other commissioning data. The DSCRO would pseudonymise the linked data prior to sharing with any CCGs or data processors. It was anticipated that in the near future an application would be brought to IGARD to request approval for the DSCRO to disseminate this pseudonymised data to an applicant.

IGARD requested further information about the specific Directions relating to this collection of data, and confirmation of what date the Direction had been agreed by the NHS Digital board. In addition it was suggested that NHS Digital should consider updating their privacy notice to include the collection of this data, and that any future applications should clearly state what information had been made available to the general public about this use of social care data.

A query was raised about a statement within the briefing paper that NHS Digital would be required to 'anonymise the datasets in line with the ICO Code of Practice', as it was not expected that this would permit the dissemination of pseudonymised data without further steps being taken to ensure that it would be anonymised in context (such as restricting linkage to other data). A further query was raised in relation to the different models currently used to share data between Local Authorities and CCGs, which could include identifiable data flowing from the Local Authority to a data processor.

Action: 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.

3 Any other business

No other business was raised.

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.	Open
27/04/17	IGARD Chair to contact the NHS Digital Caldicott Guardian regarding GPs' data controller responsibilities for fair processing around risk stratification.	Dhillon Deputy Caldicott Guardian.		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 IGARD within the following two weeks. 24/08/17: The paper was in the process of being updated based on recently published ICO guidance. 14/09/17: Ongoing. IGARD noted that given the amount of time that	Open

15/06/17	Data Services for Commissioners to work with NHS	Stuart	had passed, they would consider starting to note this on relevant applications where a data storage location was not listed as a data processor. 29/06/17: Ongoing. It was suggested it would be helpful to discuss	Open
10/00/17	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.	Richardson	this at an upcoming educational session. 14/09/17: Ongoing.	Орон
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	03/08/17: It was thought that this had now been completed. IGARD requested an email summary of the action taken so that the action could be closed. 14/09/17: An email had been circulated confirming that the standard DARS approach would be adopted. IGARD noted that a query had been raised out of committee about a particular application where this had not been applied entirely consistently and it was agreed this should be raised with the team in relation to that specific application.	Closed
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	14/09/17: It was confirmed this would be discussed at the October education session.	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	10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks. 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. 31/08/17: IGARD were notified that the requested written confirmation should be provided within one day. 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.	Open
20/07/17	Garry Coleman to categorise different standard	Garry	14/09/17: Ongoing.	Open

	lengths of indicative data retention periods for general research and clinical trials, with appropriate justification.	Coleman		
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	10/08/17: Ongoing. It was thought that this action might be addressed within the context of a forthcoming paper on a risk-based approach to application, which it was anticipated would be brought to IGARD for discussion soon. 24/08/17: Ongoing, pending wider work on a risk-based approach. 14/09/17: 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	14/09/17: 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		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		Open

Appendix B: Out of committee report (as of 08/09/17)

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-35531- X3Y7Q	London Borough of Enfield	24 th August 2017	 Updating section five of the application to reflect the controls around downloading data as described in the abstract. Section five of the application should be updated to more clearly reflect the special conditions described in section six. 	IGARD Chair	IGARD Chair	N/A
NIC-388486- D9M5N	University of Oxford	31 st August 2017	The application should be updated to provide a clearer explanation of the indicative data retention period, with this period to be updated in line with relevant legislation regarding data retention in clinical trials.	IGARD Chair	IGARD Chair	N/A
NIC-91878- Y4M2P	Guy's and St Thomas' NHS Foundation Trust	31 st August 2017	 The applicant should work with NHS Digital to update their fair processing material to an appropriate standard. In particular this should amend misleading statements that they will not attempt to reidentify individuals, given that NHS numbers will be disseminated for one cohort, and should describe the processing activities involved for both cohorts, describe the sources from which the study will receive data about the participants, and explain more clearly the cohort subset referred to. The special condition requiring the applicant to publish an agreed fair processing notice 	IGARD quorum	IGARD quorum	Additional comments on fair processing shared with DAO

	before data dissemination should be updated to require the applicant to allow a period of one month between the publication of this notice and when they will begin to contact consultants to request further information, to allow a sufficient period of time for individuals to opt out. The statement within the application that data will only be processed by individuals 'working under appropriate supervision' should be amended to use the current standard text restricting access to substantive employees only.
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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