Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 3 August 2017

Members: Joanne Bailey, Anomika Bedi, Nicola Fear, Jon Fistein, Kirsty Irvine (Acting Chair)

In attendance: Jane Cleave, Gaynor Dalton, Louise Dunn, Rachel Farrand (observer), Frances Hancox, James Humphries-Hart, Victoria May (observer), Stuart Richardson, Joanne Treddenick, Kimberley Watson

Apologies: Sarah Baalham, Chris Carrigan, Eve Sariyiannidou, James Wilson

1	Declaration of interests
	Nicola Fear noted a working relationship with some staff involved with the ICNARC application (NIC-46844-W5V5G) as well as the two University College London applications (NIC-86954-Y0R2N and NIC-148100-6RFK9). It was agreed this did not represent a substantive conflict of interests.
	Review of previous minutes and actions
	The minutes of the 27 July 2017 IGARD meeting were reviewed and subject to two minor changes were 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).
	There was a discussion about the out of committee process and it was agreed that in the absence of the IGARD Chair, the member or members acting as Chair should agree who would review application conditions returning out of committee.
2	Data applications
2.1	Institute for Fiscal Studies – Health Survey for England (Presenter: Steve Webster) NIC-
2.1	<u>30107-M5Z4Q</u>
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2.1	<u>30107-M5Z4Q</u>

Discussion: IGARD queried the description within the application of general practice data flowing into a ring-fenced area within the CCG; it was confirmed that the consented data and social care data would also flow this way and IGARD asked for the application to be updated to reflect this. In addition it was agreed that the description of social care data flows should be amended to be clear that data could flow in identifiable form from the Local Authority into the ring-fenced area, or could be pseudonymised by the Local Authority prior to flowing into the CSU. IGARD queried the legal basis for identifiable social care data to flow and it was explained that the CSU would act as a data processor on behalf of the Local Authority and the CCG to process this data. IGARD also queried a statement within the application that pseudonymised GP data would be sent to the CCG, as it was noted that in fact identifiable data would be sent to the CCG's ring-fenced area.

IGARD discussed a statement within the application that the data controller and processors would only have access to records of patients of registration within the CCG, as it was noted that these organisations were likely to hold other data under separate agreements. It was acknowledged that this wording was part of the standard CCG application template but it was suggested this wording should be amended slightly.

IGARD noted that the application stated that the CCG's privacy notice had passed the nine point check, but that the privacy notice checklist provided with the application stated that the privacy notice had failed this check recently. The importance of accuracy within applications was emphasised. It was agreed the application should be corrected and in addition the standard special condition wording around privacy notices should be updated to incorporate the current IGARD advice wording.

A query was raised about the expected additional benefits from the proposed data linkage; it was confirmed that a number of additional benefits were listed within the application, but that these had not been highlighted as amendments to the standard template text.

There was a discussion about the role of the CCG as both data controller and data processor in the described data flows, and IGARD queried whether it was accurate to describe a single organisation as both controller and processor for the same flow of data. It was agreed this should be discussed further with the IG Advisor as a generic issue rather than in relation to this specific application.

Outcome: Recommendation to approve, subject to:

The CCG should update their privacy notice in line with NHS Digital's nine criteria.

The description of data flowing into a ring-fenced area should be amended to be clear this includes consented and social care data as well as GP data, and the described flow of social care data should be updated to be clear there are two different arrangements in place. The described flow of social care data should be updated to be clear this is shared as part of a data processing agreement. A statement that the CSU will receive pseudonymised GP data should be amended to be clear that identifiable GP data will be received into the ring-fenced area.

The statement that the data controller and processor will only have access to data for residents of the CCG should be updated to reflect the arrangements in place. The special condition wording around the CCG privacy notice should be updated to reflect the current IGARD advice wording.

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

Action: Joanne Treddenick to report back to IGARD on whether organisations can be described as data controllers and data processors within an application for the same data.

2.3	Group of 8 CCGs ¹ (Presenter: James Humphries-Hart))
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Application: This application requested pseudonymised SUS and local flows data for the purpose of commissioning to support the Sustainable Transformation Footprint. It was noted that South West Central CSU and Carnall Farrar would act as data processors, and that this was in addition to existing data sharing agreements for the CCGs. IGARD were informed that some of the CCGs within the group had not yet passed the privacy notice nine point review.

Discussion: IGARD queried the security assurances for Carnall Farrar as it was noted that the summary section of the application referred to a need for this organisation to complete a penetration test within three months, but did not confirm whether NHS Digital had been content to accept the security assurances provided. It was agreed that more information should be provided about this with an explanation of why it was considered appropriate to release data prior to this test taking place.

It was agreed the application should be updated to incorporate the standard template wording regarding not attempting to re-identify the data or to link with record level data, as well as whether patient objections would apply, and the special condition wording about privacy notices should be updated to include the current IGARD advice wording. In addition it was noted that a table within the summary section of the application would need to be updated to reflect that identifiable data for risk stratification and invoice validation was not requested as part of this application.

IGARD queried a statement within the application that the data was pseudonymised and therefore 'not considered as personal data' in relation to fair processing. It was agreed that this wording was unhelpful and that it should be removed from the application. There was a discussion about the legal basis for NHS Digital to disseminate data under the Health and Social Care Act 2012 and it was agreed the application should be amended to list the correct sub-section of the Act.

Outcome: Recommendation deferred, pending:

Further information about NHS Digital's review of Carnall Farrar's security arrangements with clarification why NHS Digital is content for data to flow prior to the Penetration Test taking place.

The CCGs should update their privacy notices in line with NHS Digital's nine criteria.

The legal basis for the dissemination of pseudonymised data should be updated to refer to section 261(2)(b)(ii) of the Health and Social Care Act 2012. The special condition wording around the CCG privacy notice should be updated to reflect the current IGARD advice wording. Section five of the application should be amended to include the standard template wording regarding patient objections, restrictions on data linkage and that the applicant will not attempt to re-identify data. A statement that the data is not considered personal data should be removed from the Fair Processing section. A table in the summary section indicating that data is requested for invoice validation and risk stratification should be corrected as that is not part of this application.

2.4 <u>University College London - Critical Care Health Informatics Collaborative (Presenter: Gaynor Dalton) NIC-27803-W8G1B</u>

Application: This application requested Hospital Episode Statistics (HES) data linked to a

¹ NHS Brighton & Hove CCG NIC-91808-P5Z1F; NHS Coastal West Sussex CCG NIC-91799-G0T9X; NHS Crawley CCG NIC-91838-H0B9N; NHS East Surrey CCG NIC-91865-Y2L1H; NHS Eastbourne, Hailsham and Seaford CCG NIC-91866-V4R5J; NHS Hastings & Rother CCG NIC-91825-W4M1H; NHS High Weald Lewes Havens CCG NIC-91827-P6J6X; NHS Horsham & Mid-Essex CCG NIC-91871-D2W1N

specific cohort of patients from five participating hospital trusts, and it was noted that this was intended to be a pilot project to review the long term impacts of critical care. The applicant proposed to consider requests from third party organisations, and if the requested purpose was appropriate to provide 'dummy data' for the third party to analyse; the applicant would then run the third party's query on the real data and provide aggregated outputs with small number suppression to the third party organisation.

Discussion: IGARD queried the involvement of third party organisations and whether this could include commercial organisations, as it was noted that the application stated that the proposed use of data was not in any way commercial. IGARD were informed that requests from third parties to use the data would be reviewed by a management team including representatives from the participating trusts and lay representation, and that this team would determine whether or not the request was appropriate. Any outputs to the third party organisations would then be aggregated and have small number suppression applied prior to dissemination. IGARD noted that the study protocol listed the criteria that would be applied to these third party requests, which included that the data would be used solely for research and intended for patient benefit. It was agreed the application should be amended to reflect these criteria.

IGARD noted that a 'supporting document 2' seemed to be missing from the application pack and it was clarified that this had been an out of date data flow diagram. IGARD requested sight of a more up to date data flow diagram. An incorrect supporting document number was noted within the application and it was agreed this would be corrected.

There was a discussion of the process to provide patients with information about data processing, and some concerns were raised about how appropriate it was to provide this type of information while a patient was within a critical care unit. However it was acknowledged that these concerns needed to be balanced with the need to provide information to patients in a timely manner to allow them to be fully informed and to have the opportunity to opt out.

The potential benefits of this work were noted and it was felt that these were more clearly described within the study protocol provided as a supporting document. It was suggested that some of the detail provided within the protocol should be incorporated into the application.

IGARD noted that the application described University College London as sole data controller, but that the study section 251 support referred to joint data controllers. It was confirmed that University College London would be the sole data controller for the HES data provided by NHS Digital. IGARD noted that the application referred to the section 251 support as providing a legal basis 'to cover the data flow' and suggested this wording should be amended to be clear which data flows this covered. In addition it was agreed the application should be updated to list the identifiers that would flow to NHS Digital.

A reference to publishing results at the end of 2016 was queried and IGARD suggested that this wording should either be updated or removed. It was agreed that a special condition relating to the IG Toolkit should be removed from the application, as the applicant's version 14 submission had been reviewed as satisfactory.

Outcome: Recommendation to approve.

IGARD requested sight of an up to date data flow diagram.

The outputs and benefits sections should be amended to reflect more of the information provided in a supporting document. A statement in the abstract that section 251 support is in place should be amended to state which data flows are covered. Section 5 should be amended to list the identifiers that will be sent to NHS Digital. The special condition wording relating to the IG Toolkit should be removed as the applicant's version 14 submission has now been reviewed. Section five should be updated to describe the controls around access to data as set out in the protocol, and include a statement that UCL should only approve third parties projects to make use of data for research that is intended to provide patient benefits. A

	reference to publication being due in 2016 should be updated or removed if this is no longer applicable.
	The applicant should update their DPA registration to cover processing data about patients, rather than solely patients of NHS partner hospitals.
	It was the view of IGARD that this application would not be appropriate for renewal by IAO and
	Director delegated authority.
2.5	Intensive Care National Audit & Research Centre (ICNARC) - Psychological Outcomes following a nurse-led Preventative Psychological Intervention for critically ill patients (POPPI) cluster (Presenter: Louise Dunn) NIC-46844-W5V5G
	Application : This was a new application requesting general practice code and date of last posting from Personal Demographics Service (PDS) data. IGARD were informed that due to an error the application currently did not list the correct subsection of the Health and Social Care Act 2012 under legal basis and it was noted this would be corrected.
	Discussion : IGARD requested further information about the field 'date of last posting' and it was explained that this indicated an individual had left the NHS and was used by researchers to give an indicator of an individual's date of death, but that the field could also be used for other reasons such as emigration. It was agreed it would be helpful to explain this field more clearly in future applications. A query was raised about the intention to retain data for ten years and IGARD asked for the application to be amended to confirm whether data would be destroyed once the described work had been completed.
	There was a discussion about the applicant's security assurances and IGARD were informed that the ISO 27001 had been reviewed by NHS Digital as being acceptable subject to the client conducting a risk assessment, which had been completed. There was also a discussion of the backup services provided by Red Technology UK and Disaster Recovery Ltd and IGARD asked for a statement to be added to the application that these organisations would not access the data provided by NHS Digital, in line with the assurances provided for similar storage arrangements.
	The fair processing materials were discussed and IGARD noted that the information provided incorrectly referred to participants 'opting out', which should be more accurately described as withdrawing their consent to participate. In addition it was suggested that the consent materials should be updated to include information about how a participant could withdraw their consent at a later date if they wished to do so.
	Outcome : Recommendation to approve. The legal basis should be updated to refer to section 261(2)(c) of the Health and Social Care Act 2012. A statement should be added to section 5 that Red Technology UK and Disaster Recovery UK employees will not access the data. The indicative data retention period should be updated to reflect whether data will be destroyed once the current work is completed. The applicant organisations should update their DPA registrations to cover processing data about patients.
	IGARD advised that the fair processing information should be updated to refer to how to withdraw consent rather than describing this as opting out. In addition IGARD noted the consent forms should be updated to include how patients can withdraw consent.
2.6	University College London - MR1b Health and Development Study: Section 251 Cohort Members (Presenter: Kimberley Watson) NIC-86954-Y0R2N
	Application : This application was presented as a linked application alongside NIC-148100- 6RFK9, with this application being for the portion of the cohort who were covered by section 251 support whereas the other application covered the consented cohort. IGARD were

informed that this was a long-running study that had been in receipt of data since approximately 1971.

This application relating to the section 251 cohort requested Medical Research Information Service (MRIS) data including list cleaning and cause of death, as well as retention of previously provided Scottish registration data. It was noted that Approved Reesarcher accreditation and Microdata Release Panel approval were in place for the use of ONS mortality data. Following list cleaning the applicant would seek to re-contact the participants who had been lost to follow-up and invite them to continue participating in the study, as well as inviting them to consent to future participation. It was noted that approximately 40% of the overall cohort had been lost to follow-up.

Discussion: IGARD acknowledged the significance of this study and the important benefits that could arise from this use of data.

Some concerns were raised about the legal basis to share address details, as from the supporting documents provided it could not be clearly evidenced that the study section 251 support included sharing participant address details. IGARD were informed that the applicant considered this to be included in the section 251 support, and that this could be inferred from the section 251 application form, but IGARD noted that the section 251 application did not explicitly request address and that in a number of places in that application where address would normally be listed or ticked this did not seem to have been included.

IGARD queried the legal basis for the applicant to continue to hold Scottish registration data as this was currently unclear within the application. IGARD also queried a reference to data about parental deaths and it was agreed this should either be clarified or removed from the application.

It was noted that the applicant should update their DPA registration wording to refer to processing data about patients, rather than solely patients of partner hospitals, as IGARD noted that the participants of this study would be from across the country rather than only being patients at partner hospitals.

Fair processing was discussed and IGARD noted that this section of the application should be updated to reflect the specifics of this cohort who had been lost to follow-up, rather than referring to details that were more applicable to the consented cohort. In addition IGARD suggested that the study fair processing information should be reviewed against NHS Digital's nine minimum criteria for privacy notices. There was a brief discussion of newsletters and it was agreed the application should be updated to confirm that an updated newsletter would be issued to participants following list cleaning.

It was agreed that the application should be updated to include a statement that record level data would not be onwardly shared, as it was noted that this was not part of the current application. In addition the application should be updated to include the Microdata Release Panel approval details.

IGARD noted that section five of the application made use of some technical terms such as 'epigenomic and metabolomic factors' which would likely not be easily understood by a lay audience, and suggested that in future applications the applicant should endeavour to use clearer language that could be understood by the general public when published as part of the data release register.

A query was raised about the Research Ethics Committee (REC) approval for this study and whether it was necessary to update this approval to cover this list cleaning. It was agreed the application should be amended to be clear that this was not necessary. A further query was raised about the backup storage arrangements described in the application and confirmation was requested that NHS Digital was content with these arrangements. In addition IGARD

	noted that the application should be updated to state that the Data Sharing Framework Contract (DSFC) for University College London had been extended.
	 Outcome: Recommendation deferred, pending: Clarification of the applicant's section 251 support and how this is considered to cover the provision of address details.
	Confirmation was requested of the legal basis for the applicant to continue to hold Scottish Registration data. Confirmation was also requested of whether the study privacy notice is considered to meet NHS Digital's nine criteria. The application should be updated to confirm that an updated REC review is not required to cover this list cleaning. The description of the study's fair processing efforts should be amended to specifically apply to this application rather than the consented cohort, and to state that an updated newsletter will be sent to the cohort following list-cleaning. A statement should be added to section 5 that there will be no onward sharing of data as part of this application. A reference to parental deaths should be clarified or removed. The Microdata Release Panel details should be added to clarify the arrangements and to be clear this has been reviewed by NHS Digital as part of the security assurance review. The application should also be updated to reflect that the DSFC has been extended. IGARD advised that the applicant should update their DPA registration to cover processing data about patients, rather than solely patients of NHS partner hospitals. IGARD noted the importance of this study and the need for the applicant to continue to hold data. In light of this it was suggested that NHS Digital might wish to consider a short term extension to permit the continued retention of data while work was undertaken to address the queries raised by IGARD.
2.7	University College London - MR1a Health and Development Study: Consented Cohort Members (Presenter: Kimberley Watson) NIC-148100-6RFK9
	Application : This application (linked to NIC-86954-Y0R2N) was for the portion of the MR1 cohort who had consented, with HES data requested for the first time in addition to the MRIS data already disseminated.
	It was noted that the legal basis for mortality data listed in section three of the application would be updated to refer to section 261(7) of the Health and Social Care Act 2012.
	Discussion : IGARD reiterated a number of the comments raised in relation to the linked application NIC-86954-Y0R2N. In particular it was noted that a reference to data on parental deaths should be clarified within the application.
	There was a discussion of the consent form and patient information materials, and IGARD noted that while the actual consent form clearly described the data processing and linkage involved this was less clear from the patient information sheet. However it was acknowledged that the patient information sheet did not contradict the consent form or rule out this type of data processing, and IGARD agreed that the steps taken to provide further information via fair processing seemed appropriate.
	IGARD noted that the consent form provided was version three, which was the same version that had been reviewed by HRA CAG. Confirmation was requested that only individuals who had consented using version three of the consent materials would be included within this consented cohort for this application, as individuals who had consented using older versions would be expected to be covered by the section 251 support to enable the study to seek updated consent.
	 Outcome: Recommendation to approve, subject to: Confirmation of whether the study privacy notice is considered to meet NHS Digital's
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	nine criteria.
	The application should be amended to confirm of the legal basis for the applicant to continue to hold Scottish Registration data. The legal basis listed in section 3 should be updated to refer to section 261(7) of the Health and Social Care Act 2012. The application should be amended to be clear that the consented cohort only includes individuals consented using version 3 of the consent materials. A statement should be added to section 5 that there will be no onward sharing of data as part of this application. A reference to parental deaths should be clarified or removed. The Microdata Release Panel details should be added to clarify the arrangements and to be clear this has been reviewed by NHS Digital as part of the security assurance review. The application should also be updated to reflect that the DSFC has been extended. IGARD advised that the applicant should update their DPA registration to cover processing data about patients, rather than solely patients of NHS partner hospitals. It was agreed the above condition would be reviewed out of committee by the IGARD Chair.
3	Any other business IGARD were reminded that the 7 September 2017 meeting had been cancelled, and that the monthly education session would therefore be held on 14 September 2017.

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	 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. 20/12/16: It was anticipated an update would be available in mid-January. 10/01/17: Ongoing. It was agreed that this action would be taken forward by Alan Hassey rather than Peter Short. 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. 31/01/17: Ongoing. It was agreed the IGARD Chair would request an update on progress of this action. 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. 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. 11/05/17: This action was not discussed due to time restrictions. 18/05/17: IGARD received a verbal update on work underway to develop 'dummy data' for the purpose of developing tools and algorithms. 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 	Open

			and to raise the topic again at a later date. 03/08/17: 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	03/08/17: 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. 03/08/17: 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. 	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. 03/08/17: 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	Garry Coleman	03/08/17: Ongoing.	Open

	subsections, such as section 261(2)(b)(ii).			
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.	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 03/08/17: Ongoing.		
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	03/08/17: 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	03/08/17: 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	03/08/17: Ongoing.	Open
03/08/17	Joanne Treddenick to report back to IGARD on whether organisations can be described as data controllers and data processors within an application for the same data.	Joanne Treddenick		Open

Appendix B: Out of committee report (as of 28/07/17)

These applications were previously recommended for approval with conditions by IGARD (or recommended with caveats by DAAG), 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 updated application by:	Notes of out of committee review (inc. any changes)
NIC-346693	University College London	06/07/17	 Confirmation from HRA CAG of whether the study's section 251 support has been renewed. 	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:

• None