

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 20 July 2017

Members: Nicola Fear, Jon Fistein, Kirsty Irvine, Eve Sariyannidou, James Wilson

In attendance: David Bryant, Dave Cronin, Garry Coleman, Gaynor Dalton, Jen Donald, Louise Dunn, Rachel Farrand (observer), Frances Hancox, Louise Hill, Stuart Richardson, Kimberley Watson, Vicki Williams

Apologies: Sarah Baalham, Joanne Bailey, Anomika Bedi, Chris Carrigan

1	<p>It was agreed that Kirsty Irvine would act as chair for this meeting.</p> <p>Declaration of interests</p> <p>James Wilson declared a potential conflict of interest in the University College London applications (NIC-49297, NIC-180665, NIC-393510) due to his employment by University College London but noted no other specific link to the applications.</p> <p>Nicola Fear declared a potential interest in NIC-29827 University of Oxford, NIC-78397 University of Oxford, NIC-147982 University of Liverpool and NIC-180665 University College London due to various working relationships but it was agreed that these potential interests did not constitute a substantive conflict of interests.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 13 July 2017 IGARD meeting were reviewed and it was agreed that the discussion under Any Other Business should be updated to more clearly reflect that while IGARD noted the update provided, they did not recommend to disseminate data or otherwise formally agree with the view reached by NHS Digital regarding the legal basis for the National Audit Office application. Subject to this change 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>Queries were raised regarding NIC-13925-Q7R2D IMS Health Ltd, as it had been agreed by IGARD that the conditions for this should be considered out of committee by a quorum of IGARD members but in practice the conditions had been signed off by the Director of Data Dissemination following a discussion with the IGARD Chair. It was agreed that the Out of Committee Report template should be amended to include information about who IGARD had initially specified should consider the conditions for an application.</p>
2 2.1	<p>Data applications</p> <p><u>University of Oxford - The role of patient factors, surgical factors and hospital factors upon patient outcomes and NHS costs in the treatment of upper limb musculoskeletal conditions (Presenter: Louise Dunn) NIC-29827-Q8Z7Q</u></p> <p>Application: This was a new application requesting pseudonymised Hospital Episode Statistics (HES) as well as Office for National Statistics (ONS) mortality data including the</p>

<p>identifier date of death, for a cohort of individuals selected by NHS Digital according to clinical codes relating to specific conditions.</p> <p>IGARD were informed that evidence of Microdata Release Panel approval should have been provided as a supporting document but had been inadvertently omitted from the application papers; it was agreed this would be circulated following the meeting.</p> <p>Discussion: IGARD queried the wording used in this application to restrict the use of data to substantive employees, and it was suggested that this should be amended to reflect the current standard wording. The role of the Botnar Research Centre was queried; it was explained that this centre was part of the University of Oxford and it was agreed their involvement should be explained more clearly within the application. It was also agreed that a statement that 'only authorised users' would have access to data should be amended to be clear that only the specific ONS users referred to within the application would have access to the ONS mortality data, and a reference to making 'smaller extracts' available for analysis should be clarified.</p> <p>IGARD discussed the amount of data requested. It was agreed that a clearer justification was required for the number of data years requested, particularly as it was noted that some of the conditions described had only been in use since roughly 2012 and it was therefore unclear why so many years of data previous to this would be required. The use of geographical data was also discussed and IGARD queried whether the inclusion of geographical fields could lead to data being more likely to be re-identified; it was clarified that the lowest level of geographical data provided would be Lower Super Output Area (LSOA). IGARD asked for the application to be updated to specify which geographic fields would be provided as this was currently not clear within the application, and also requested an explanation of how the applicant considered this data to be anonymised in context. In addition it was agreed the application should include a statement that the applicant would not attempt to re-identify individuals from the data available to them.</p> <p>The indicative data retention period was queried as IGARD noted that section five of the application referred to retaining data at the Botnar Research Centre 'for a further five years', but that the research protocol appeared to state that data would be retained for three years and that section eight of the application listed the indicative data retention period as three years. It was agreed this should be clarified for consistency. In addition IGARD asked for the application to be amended to include a statement that the applicant would not link record level data, and that there would be no onward disclosure of record level data.</p> <p>Outcome: Recommendation to approve, subject to:</p> <ul style="list-style-type: none"> • Providing a clearer justification for why 20 years of data are required, particularly when considering procedures that have only been in use for roughly five years. • Providing a clearer explanation of how geographical data will be used and how the applicant considers that this data will be anonymised, with confirmation of which geographical fields will be provided. Section five of the application should be updated to include a statement that the applicant will not attempt to re-identify individuals within this data. • Provision of evidence of the Microdata Release Panel approval. • The planned data retention period should be clarified to ensure this is described consistently within the application. <p>A reference to substantive employees should be amended to use the current agreed wording, and a reference to 'only authorised users' accessing data should be amended to be clear this refers to Approved Researchers within the organisation. References to the Botnar Research Centre should be clarified. Section five should be amended to include a statement that data will not be linked to any other record level data, and that there will be no onward disclosure of record level data.</p> <p>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</p>

	<p>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. It was agreed the above conditions would be considered out of committee by IGARD.</p>
2.2	<p><u>National Institute for Cardiovascular Outcomes Research (NICOR) - Myocardial Ischaemia National Audit Project (MINAP) (Presenter: David Bryant) NIC-64572-X0Q4D</u></p> <p>Application: This application requested an amendment to an existing agreement to change the data processor as well as the processing and storage location, due to NICOR now being hosted at Barts Health NHS Trust instead of University College London. It was noted that the application leading to the current agreement had been considered by DAAG at the 31 January 2017 meeting and recommended for approval.</p> <p>Discussion: IGARD queried the process to transfer data from University College London to Barts Health and it was confirmed that the data was now hosted on a server owned by Barts Health, with data held on the previous University College London server having been appropriately destroyed .</p> <p>The assurances regarding HQIP's security arrangements were noted but IGARD asked for the application to be amended to include the date that the HQIP System Level Security Policy (SLSP) was reviewed and approved by NHS Digital.</p> <p>Outcome: Recommendation to approve. The application should be amended to include the date that the HQIP SLSP was reviewed and approved by NHS Digital. 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.</p>
2.3	<p><u>London Borough of Richmond Upon Thames Council - HDIS (Presenter: Gaynor Dalton) NIC-10459-G9T3P</u></p> <p>Application: This application was to amend an existing agreement for access to the HES Data Interrogation Service (HDIS), with the requested amendment being to include London Borough of Wandsworth as an additional data controller. IGARD were informed that this was due to a shared staffing arrangement between the two councils that meant the team using HDIS for public health purposes would now work as a single team across both boroughs. It was noted that both councils had previously had agreements to receive HES extracts for public health purposes but that for practical reasons both councils would instead use HDIS; IGARD were informed that both councils had destroyed the HES extracts previously provided for public health, but that data destruction certificates had not yet been provided.</p> <p>Discussion: There was a discussion of whether the two councils should be considered joint data controllers or data controllers in common, and IGARD suggested it would have been helpful to receive additional evidence of the shared staffing arrangements in place between the two organisations. IGARD requested confirmation that the specific members of staff who would access HDIS were substantive employees of both councils, as it was considered that this would indicate that both organisations would be jointly responsible for use of the data.</p> <p>IGARD agreed that a special condition should be added to the application that the new</p>

	<p>agreement granting HDIS access should not be finalised until both organisations had provided data destruction certificates for the previously disseminated HES data. IGARD noted that the current special condition wording around destroying HES data referred to ‘the applicant’ without specifying which of the two organisations this related to and it was agreed this wording should be clarified. In addition IGARD noted that the standard application wording around the role of the Director of Public Health as Information Asset Owner (IAO) for the HES data should be amended to appropriately reflect the shared staffing arrangement and the roles of both Directors of Public Health.</p> <p>Outcome: Recommendation to approve subject to:</p> <ul style="list-style-type: none"> • Confirmation that the individuals who will access the data are substantive employees of both Councils. • Adding a special condition that data should not be disseminated until the relevant data destruction certificates have been provided. <p>The special conditions referring to ‘the applicant’ agreeing to destroy HES data should be amended to clarify which organisations this refers to. References to the Director for Public Health acting as IAO for the HES data should be amended to refer to the Directors for Public Health for both organisations.</p> <p>It was agreed the above conditions would be considered out of committee by IGARD.</p> <p>2.4 <u>NHS South, Central and West CSU - HDIS (Presenter: Kimberley Watson) NIC-99675-X5S7X</u></p> <p>Application: This application was for access to HDIS.</p> <p>It was noted that it had come to light in 2016 that this CSU had downloaded record level HES data from HDIS and forwarded this to another NHS organisation, which was considered a major breach of their data sharing agreement and NHS Digital had therefore ceased the organisation’s access to HDIS. NHS Digital had carried out a data sharing audit in July 2016 and the published audit report was provided to IGARD alongside the application. It was noted that an additional data sharing audit had taken place in December 2016 which had focused on a data processor used by the CSU, and that the report of that audit had not yet been published; IGARD were notified that the data processor in question was not involved in the current application. In addition it was noted that the functionality within HDIS had now been restricted so that if access was granted, the CSU would be unable to download record-level data.</p> <p>Discussion: IGARD noted that section three of the application should be updated to also reflect the relevant subsection of the Health and Social Care Act 2012.</p> <p>IGARD acknowledged that the original audit report concluded that ‘there is low risk of a breach of information security, duties of care, confidentiality or integrity’ but also noted that the audit report stated that the CSU ‘could not provide assurance to the Audit Team that data assets were subject to effective management and control as required by their own policies and procedures and the HDIS Data Sharing Agreement’. IGARD raised concerns that they had not been provided with a copy of the more recent audit report from December 2016, and in addition that the corrective action plan relating to the earlier audit had not yet been validated by NHS Digital. It was therefore felt that sufficient evidence had not been provided that the issues brought to light by the previous data breach had been satisfactorily addressed.</p> <p>Outcome: Not recommended for approval.</p> <p>IGARD gave consideration to the substantive content of the audit report and in particular the statement that “The CSU could not provide assurance to the audit team that data assets were subject to effective management and control as required by their own policies and procedures and the HDIS data sharing agreement” raised concerns about the governance controls in place for the applicant to have access to data. It was noted that the corrective action plan had not yet been validated by NHS Digital and that IGARD had not had sight of the audit report</p>
--	---

from the second audit that took place in December 2016 as this had not yet been published. The legal basis under the Health and Social Care Act 2012 should be amended to refer to the relevant subsection.

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.

2.5

Group of 5 CCGs¹ (Presenter: Stuart Richardson) GA01-SC-AMD

Application: This was a new application to permit the sharing of Children and Young People's Health (CYPHs) and Maternity Services Dataset (MSDS) data between five CCGs for the purpose of commissioning, with South, Central and West CSU acting as data processor. IGARD were informed that three of the CCG privacy notices had been reviewed as passing NHS Digital's nine point check but that two had failed the check. In addition IGARD were informed that section three of the application did not currently list the other types of data held by the CCGs for commissioning purposes but that the application would be updated to incorporate this information.

Discussion: IGARD queried the information governance arrangements that would be in place for data sharing between the CCGs. It was noted that the Service Level Agreement provided as a supporting document did not provide the same types of detail about information governance that had been included in the agreements used by other CCGs carrying out the same type of data sharing and IGARD suggested that these five CCGs should establish appropriate information governance arrangements in line with the type of agreements used by comparable CCGs.

There was a discussion of the CCG privacy notices and IGARD raised that these contained potentially misleading references to withdrawing consent, and in addition did not describe sharing pseudonymised data with other CCGs as described in this application.

IGARD noted the involvement of South, Central and West CSU given the discussion earlier in the meeting around previous data breaches and data sharing audits involving that organisation. It was acknowledged that for this application the CSU would be acting as a data processor rather than a data controller; however IGARD requested an update from NHS Digital on the management of risk around this CSU acting as a data processor for CCGs. IGARD queried the described outputs and suggested that the application wording should be amended to ensure that only outputs specifically related to the purpose of this application (and the use of CYPHs and MSDS data) should be included.

A query was raised about the different pseudonymised datasets already provided under separate agreements and IGARD requested confirmation that the data under this application would be disseminated using a different pseudonymisation key.

Outcome: Recommendation to approve, subject to:

- The CCGs should update their privacy notices in line with NHS Digital's nine criteria and in particular should clarify references to withdrawing consent, descriptions of data as anonymised, and explain how data will be shared between the CCGs.
- The CCGs should establish an appropriate data sharing agreement between them to confirm what information governance controls will be in place for the use of this shared

¹ NHS North Hampshire CCG NIC-105590-Y6G8Z; NHS North East Hampshire and Farnham CCG NIC-105537-G2C0J; NHS South Eastern Hampshire CCG NIC-105591-R7X9G; NHS Fareham and Gosport CCG NIC-105592-W1P4M; NHS West Hampshire CCG NIC-105594-Y9L1Q

<p>2.6</p>	<p>data, along the lines of similar agreements used by other CCGs</p> <ul style="list-style-type: none"> Confirmation that the data disseminated under this application will be pseudonymised using a different key to the pseudonymised data already provided to the applicants under separate agreements. <p>The outputs section should be amended to ensure that the standard outputs listed are all relevant to the specific datasets requested in this application, and section three should be updated to list the data already held by these CCGs for commissioning purposes. It was agreed these conditions would be considered out of committee by IGARD.</p> <p>Action: 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.</p> <p><u>University College London - Centre for Longitudinal Studies Birth Cohort Studies Data Linkage: National Child Development Study (Presenter: Jen Donald) NIC-49297-Q7G1Q</u></p> <p>Application: This was a new application requesting the linkage of pseudonymised HES data to the 'Aged 50 Cohort' who had consented to the use of health data for research purposes. It was intended that a future amendment application would be submitted to request to make the linked research data available to other researchers, but the current application only requested the use of data by University College London. IGARD were informed that the study's fair processing materials had been reviewed against NHS Digital's nine criteria and had passed with the exception that University College London was not explicitly identified as a data controller.</p> <p>Discussion: IGARD discussed the identifiers that the applicant would provide into NHS Digital for linkage and noted a reference to NHS number, despite the fact that this did not seem to be covered by the participant consent. It was agreed the application should be amended to remove references to providing NHS number to NHS Digital. There was a discussion of whether the consent materials provided an appropriate legal basis for the planned linkage; on balance IGARD agreed that while the word 'linkage' was not explicitly used, this did seem to be implied by the description of using healthcare data. In addition it was acknowledged that participants had been actively involved in the study for a long time and it was considered that participants would not be surprised by the linkage of health data based on the information they had been provided with.</p> <p>IGARD discussed the fair processing information currently available to participants and in general noted their contentment but agreed that this would need to be updated to reflect University College London's role as data controller for this healthcare data. IGARD noted that the website already referred to making linked data available to other researchers in future, despite the fact that this had not yet been requested or agreed.</p> <p>It was agreed that the legal basis listed in section three of the application should be amended to refer to the correct subsection of the Health and Social Care Act 2012.</p> <p>There was a discussion of the indicative data retention period, as it was noted that application referred to retaining data until 2034 'in line with Department of Health guidance' but it was unclear what specific guidance this referred to. It was agreed the application should be updated to provide a clearer explanation of the reason for this. More widely it was agreed that NHS Digital should consider whether broad categories could be established to help agree what approximate length of data retention period would be appropriate for various uses of data.</p> <p>Outcome: Recommendation to approve, subject to:</p> <ul style="list-style-type: none"> The fair processing information published online should be updated to include a statement that University College London is the data controller.
------------	---

	<p>The application should be updated to remove NHS number as a field that University College London would provide to NHS Digital, as this did not appear to be covered by participant consent.</p> <p>The legal summary provided in the abstract section should be amended to clarify a reference to consent being in place for linkage. The legal basis under the Health and Social Care Act 2012 should be amended to refer to the relevant subsection. The reason for the indicative data retention period should be updated to provide a clearer explanation including explaining what guidance is referred to. It was agreed this condition would be considered out of committee by IGARD.</p> <p>Action: Garry Coleman to categorise different standard lengths of indicative data retention periods for general research and clinical trials, with appropriate justification.</p>
2.7	<p><u>University of Oxford - Long-term follow-up of Asymptomatic Carotid Surgery Trial (ACST-1) (Presenter: Dave Cronin) NIC-78397-Z1F1Q</u></p> <p>Application: This was a new application requesting identifiable HES, mental health and demographics data (including date of death) for a specific trial cohort. IGARD were informed that the cohort had consented to be part of the original study, but that section 251 support was in place for this new follow-up. It was noted that the applicant was likely to request ONS mortality data at a later date, but that this was not part of the current application.</p> <p>Discussion: IGARD discussed the applicant's fair processing efforts and the need to ensure that participants were appropriately notified of the intention to use data given the legal basis under section 251. Confirmation was requested that the updated fair processing information would be published online prior to data being disseminated, so that individuals could have an opportunity to opt out if they wished to do so.</p> <p>IGARD queried a statement within the application that data would be retained 'indefinitely'. It was agreed this wording should be amended to confirm that data would not be retained for any longer than necessary. There was a brief discussion of the study funding arrangements and IGARD requested sight of the funding grant terms and conditions.</p> <p>Outcome: Recommendation to approve, subject to:</p> <ul style="list-style-type: none"> • Confirmation that the updated fair processing information will be published before data is disseminated. • Providing a copy of the funding grant terms and conditions. <p>A reference to retaining data indefinitely should be reworded to be clear that data would not be retained for longer than necessary.</p> <p>It was agreed these conditions would be considered out of committee by IGARD.</p>
2.8	<p><u>University of Liverpool - The Roy Castle Lung Cancer Research Programme, Liverpool Lung Project (Presenter: Jen Donald) NIC-147982-J7KGV</u></p> <p>Application: This application was to merge two previous data sharing agreements requesting identifiable HES data and ONS mortality data, and additionally requesting an amendment for the receipt of cancer registry data for a specific cohort. Recruitment had begun in 1997 and IGARD were informed that the consent materials would not be considered up to current standards, but they had been deemed appropriate by ONS at the time and later by the NHS Information Centre due to the use of specific recommended wording. It was noted that the applicant had contacted HRA CAG regarding the possibility of section 251 support and had been advised that this would not be considered applicable as participant consent was in place. It was noted that the applicant's fair processing efforts were not currently considered to meet NHS Digital's nine criteria for privacy notices, and the applicant had been advised to make improvements to address this as well as updating consent materials.</p>

IGARD were informed of an error in the application as the list of planned outputs should also include the Liverpool Lung Project risk tool which was already in existence, with NHS Digital data being intended to improve and further develop the tool. It was noted that the applicant had been advised to update their DPA registration to include data about patients and the use of data for health research.

Discussion: IGARD noted that recruitment had been ongoing since 1997 and queried how the consent materials had changed over that time, particularly as it was noted that the consent material provided appeared to be dated 2016. Further information was requested about what versions of consent forms had been used at what points in time, and whether participants recruited early on had since re-consented using a more recent version of the consent form. IGARD queried whether the consent materials had previously been reviewed by DAAG but it was explained that this application had not previously been considered by DAAG. Some concerns were raised regarding ongoing recruitment as IGARD considered that the current consent form should be further updated, particularly as updated fair processing information was not yet in place. IGARD requested more detailed information about the view taken by ONS and HRA CAG that the consent materials provided a sufficient legal basis for the dissemination of data without the need for an alternative legal basis such as section 251 or Approved Researcher accreditation. Given the concerns raised it was agreed that an updated application should be submitted within the next few weeks.

IGARD queried a statement in the application that data would not be used to 'to demonstrate linked patterns of Hospital Admissions to Cancer rates or death statistics' and it was agreed this wording should be clarified. In addition it was agreed the application should be amended to more clearly state that the cohort was not solely formed of participants who had been diagnosed with lung cancer. Furthermore IGARD noted that the legal basis listed in section three of the application should be updated to include the appropriate subsection of the Health and Social Care Act 2012.

Outcome: Recommendation deferred, pending:

- Provision of all relevant consent materials from the beginning of recruitment onwards.
- Providing further information about the view taken by HRA CAG and previously by ONS that the consent materials provided an appropriate legal basis for data sharing.

A statement that the data will not be used to demonstrate linked patterns of hospital admissions to cancer rates should be clarified. The application should be amended to more clearly state that not all the cohort had been diagnosed with lung cancer. The legal basis under the Health and Social Care Act 2012 should be amended to also refer to the correct subsections.

IGARD requested that an updated application should be submitted within four weeks to address the above points, and that the updated application should including an update on plans to publish the fair processing materials and to update the consent materials for ongoing recruitment.

2.9

University of Birmingham - Adjuvant Tamoxifen Treatment - Offer -More? (ATTOM) (Presenter: Dave Cronin) NIC-148286-3RWRG

Application: This application requested a short term extension for a long running research study, with the extension permitting the applicant to continue to hold and use the data already disseminated but without any more data being disseminated until some outstanding issues had been fully addressed. In particular it was noted that sharing data with the University of Oxford would not be covered by this application and this would need to be subject to a future request and providing appropriate evidence of the contractual arrangements in place with the University of Oxford. In addition IGARD were informed that once the short term extension ended the applicant would need to provide a clearer justification for the amount of data held, more information about the planned outputs, and update their fair processing information in

order to meet NHS Digital's standard nine point check. It was noted that due to historic technical limitations the applicant had previously received latest demographic data from NHS Digital and that it was not expected that this type of data would now be disseminated.

In addition IGARD were informed that a reference to the role of the BTCU had inadvertently been removed from the application and that this had now been re-inserted.

Discussion: IGARD queried a statement in the application that the requested extension was solely to enable retention; it was clarified that the extension would permit the applicant both to retain the data and to continue to use it for agreed purposes. In addition IGARD queried a statement that the lead statistician had transferred from the University of Birmingham to the University of Oxford and it was confirmed that as no data sharing with the University of Oxford was permitted under this application, only University of Birmingham staff would be able to process the data. IGARD were informed that data had been shared with the lead statistician in the past under an honorary contract with the University of Birmingham, but that more work was required to confirm appropriate contractual arrangements to cover any further data sharing.

There was a discussion of the historic processes that had meant that when the study submitted demographic data including identifiers, NHS Digital's predecessor body had provided back the latest versions of those same demographic details from the Personal Demographics Service (PDS). IGARD queried the legal basis for this dissemination of identifiers and it was acknowledged that there would be difficulties determining which latest demographics data was still held by the study as this would have been combined with demographic data from other sources. It was reiterated that NHS Digital would not provide latest demographics data on an ongoing basis without a clearer legal basis but IGARD remained concerned about the applicant continuing to hold this data as it was not clear whether there was a current legal basis for the retention of latest demographics.

IGARD requested a clearer explanation of the legal basis relating to latest demographics data and also agreed that the updated application should provide an update on fair processing, an explanation of data minimisation and confirmation of contractual arrangements with the University of Oxford.

Outcome: Recommendation deferred, pending:

- Providing a clear explanation of the legal basis for the applicant to continue to retain and use data provided as latest available demographics, or if no appropriate legal basis then confirmation that this data will be destroyed.
- Confirming appropriate contractual arrangements between the applicant and the University of Oxford, and updating the processing activities in the application to reflect data sharing with the University of Oxford.
- The fair processing materials should be updated to be in line with NHS Digital's nine point criteria.
- Providing a clearer explanation of how data held will be minimised.

2.10

University College London - General Health & Hospital Admissions in Children Born after ART: A Population Based Linkage Study (Presenter: Jen Donald) NIC-180665-GJMW5

Application: This application was for pseudonymised HES and ONS mortality data linked to a cohort of children born via Assisted Reproductive Technologies (ART) as well as siblings conceived without ART and a control cohort. An application for this had previously been considered by DAAG on 10 February 2015 and recommended for approval but due to some delays data had not yet been disseminated to the applicant. Section 251 support was in place for the use of identifiable data, and Approved Researcher accreditation and Microdata Release Panel approval were in place for the dissemination of ONS mortality data.

Discussion: A query was raised about the inclusion of HES Critical Care data in this

2.11	<p>application, as it appeared that this had not been included in the previous application and no specific explanation was given for its addition. It was noted that the abstract section of the application incorrectly stated the date that the previous application had been considered by DAAG and IGARD suggested that it might be helpful to correct this. IGARD noted that the earlier application had referred to sharing ONS data with HFEA, but that this had been removed prior to finalising the data sharing agreement as a legal gateway for this flow of data had not been confirmed. It was agreed the current application should be amended to include a specific statement that data would not be shared with HFEA.</p> <p>It was noted that the fair processing information on the HFEA website did not currently seem to be accessible, potentially due to a broken link on the website. IGARD suggested the applicant should correct this, and also suggested that the applicant should consider how fair processing information would be made available to the control cohort.</p> <p>It was noted that the legal basis listed in section three of the application should be amended to refer to the applicable sub-section of the Health and Social Care Act 2012. In addition IGARD noted that evidence of the Microdata Release Panel expiry date had not been provided, but it was clarified that although the Microdata Release Panel details and expiry dates would be listed within applications no additional evidence would be provided as standard at the present time.</p> <p>Outcome: Recommendation to approve.</p> <p>The application should be amended to confirm whether HES Critical Care data is requested. A statement should be added to section five that data will not be shared with HFEA. The legal basis under the Health and Social Care Act 2012 should be amended to refer to the relevant subsection.</p> <p>IGARD noted that the study website currently did not seem to be working and advised the applicant to correct this and to consider how information might be made available to the control cohort.</p> <p><u>University of Manchester - Childhood Arthritis Prospective Study (CAPS) (Presenter: Dave Cronin) NIC-292331-J5B5X</u></p> <p>Application: This application was to extend and renew a recently expired data sharing agreement. IGARD were informed that the study's privacy notice did not currently meet NHS Digital's nine point check but that work was underway to relaunch the study website and the application included a special condition to meet the nine criteria by mid-September. In addition IGARD were informed that references in the application to third party collaborations only referred to sharing aggregated data with small numbers suppressed.</p> <p>Discussion: IGARD queried the special condition requiring fair processing information to be updated within two months and it was explained that the applicant intended to issue a summer newsletter to participants within that time which would provide more information about the use of data and reiterate participants' options for opting out of the study. Confirmation was requested of whether the study consent materials would also be updated, given that the application indicated that recruitment to the study would be ongoing until 'at least July 2018'. IGARD queried how recently the currently flagged cohort had given consent, and whether for example the flagged cohort only consisted of participants who had consented and been flagged by 2015 or if more recent participants were also included. Due to the concerns around consent materials and whether these were sufficient to provide an ongoing legal basis in consent, IGARD proposed that the data sharing agreement should be limited to two months only and that an updated application should be submitted once the special condition around fair processing had been addressed. The updated application would also need to clearly state the case for a legal basis in consent, as well as providing details about any updates to the consent materials for ongoing recruitment.</p>
------	--

	<p>A query was raised about the process for children to re-consent once they reached the age of 16, as it was noted that the study invited these participants to consent to continue in the study but it was unclear how frequently the study would notify NHS Digital of individuals who had chosen not to consent. It was therefore considered unclear whether the currently flagged cohort might still contain some individuals who had recently turned 16 but chosen not to give their consent to the study.</p> <p>IGARD queried the description of sharing ‘anonymised and aggregated’ data with Glasgow Caledonian University and suggested that this wording should be amended to be clear that the only data shared was aggregated with small numbers suppressed in line with the applicable NHS Digital guidance.</p> <p>IGARD discussed the potential benefits of this study and some disappointment was expressed that the application did not more clearly articulate how outputs would be disseminated to help achieve benefits. However it was acknowledged that the study might not yet be at a sufficiently advanced stage to communicate the outputs more widely.</p> <p>Outcome: Recommendation to approve for a period of two months only.</p> <p>The application should be amended to more clearly state that the current application only includes data for participants already flagged by NHS Digital before 2015, and that any future requests for data on newly recruited participants would need to provide evidence of an appropriate legal basis in consent.</p> <p>Confirmation of the process where a child turning 16 does not provide consent, and the frequency of notification from the study to NHS Digital to remove these individuals from the cohort.</p> <p>A reference to sharing anonymised data with Glasgow Caledonian University should be clarified to be clear that only aggregated data with small numbers suppressed has been shared.</p> <p>It was the view of IGARD that the updated application in two months would not be appropriate for renewal by IAO and Director delegated authority.</p> <p>2.12 <u>University College London - Policy Research Unit for Children, Young People and Families (Presenter: Jen Donald) NIC-393510-D6H1D</u></p> <p>Application: This was a renewal and amendment application for the use of pseudonymised HES and identifiable ONS mortality data, with the requested amendment being the addition of two ONS users and the application of patient objections. It was noted that this work was funded by the Department of Health and that the application remained largely unchanged since it was last considered by DAAG at the 3 March 2015 meeting.</p> <p>Discussion: IGARD asked for section three of the application to be updated to also include the relevant sub-section under the Health and Social Care Act 2012. A query was raised about Approved Researcher accreditation but it was confirmed that ONS data would be disseminated under Section 42(4) of the Statistics and Registration Service Act 2007. IGARD noted that the applicant’s DPA registration was shortly due to expire and that this would need to be renewed in order for data to continue to flow.</p> <p>It was noted that due to the timescales involved patient objections had not been applied to the data previously disseminated to the applicant, but that patient objections would be applied to the upcoming data dissemination. IGARD queried what standard process NHS Digital would follow in this situation and whether it would be possible to ensure that the applicant could not identify the individuals from the original data who had objected by comparing the two disseminations. It was noted that the application included the restriction that the applicant must not attempt to re-identify individuals from the data provided.</p> <p>Outcome: Recommendation to approve.</p>
--	---

	<p>The legal basis under the Health and Social Care Act 2012 should be amended to refer to the relevant subsection.</p> <p>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.</p>
3	<p>Any other business</p> <p><u>University of Leeds NIC-315999-W2W4C</u></p> <p>This application had been considered at the 13 July 2017 IGARD meeting, but as IGARD had not been quorate no recommendation had been made. IGARD were notified that NHS Digital had taken the decision to disseminate data to the applicant, and that the application would therefore not return to IGARD at this stage to seek a recommendation. IGARD acknowledged this update.</p>

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. 20/07/17: 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	20/07/17: 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: Ongoing.	Open
04/05/17	Robyn Wilson and Joanne Treddenick to agree updated wording for the PCMD application template on type two objections, ensuring that this is consistent with published NHS Digital information about exceptions to type two objections.	Robyn Wilson	11/05/17: The IG Advisor gave a verbal update with confirmation that in October 2016 NHS Digital had confirmed a decision that type two objections would not be considered to apply to this flow of data due to the specific legal gateways around ONS data sharing. Further work was planned to agree the specific application wording to describe this. 18/05/17: IGARD were informed by the Secretariat that Robyn and Joanne had agreed new draft wording, and that this would be circulated to IGARD for discussion out of committee. 25/05/17: The new draft wording had been circulated out of committee and members were reminded to provide any comments by email if they wished to do so. 08/06/17: There had been a further discussion of the wording by email. 15/06/17: IGARD had received an updated email response to the queries raised. IGARD were asked to provide any comments on this by the following week's meeting. 22/06/17: This was currently with an IGARD member to respond. 29/06/17: Ongoing pending a response from IGARD members. 13/07/17: It was agreed IGARD members would be reminded of the need to respond and close this action.	Closed

			20/07/17: IGARD received an email update that the majority of PCMD applications had now been renewed, and it was anticipated that by the time of the next round of renewals the position on opt outs was likely to have further evolved. It was agreed the action would be closed and reconsidered at a future date.	
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. 20/07/17: Ongoing.	Open
01/06/17	Garry Coleman to provide information about the process for applicants moving from the use of identifiable to pseudonymised data and what standard steps are taken when they opt to retain identifiable data as well as receiving new pseudonymised data.	Garry Coleman	20/07/17: An email update had been provided and the action was closed.	Closed
15/06/17	NHS Digital to provide information about the standard approach to data destruction where an applicant has been provided with data for linkage, and whether the original data should be retained as well as the linked data.	Jen Donald	20/07/17: An email update had been provided and the action was closed.	Closed
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. 20/07/17: 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	20/07/17: 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	20/07/17: 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. 20/07/17: Ongoing.	Open
13/07/17	Dickie Langley to provide an email relating to the approval of NIC-382334 National Audit Office.	Dickie Langley	20/07/17: This had been provided and the action was closed.	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	20/07/17: 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		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		Open

Appendix B: Out of committee report (as of 14/07/17)

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 state conditions to be agreed by:	Conditions agreed by:	Notes of out of committee review (inc. any changes)
NIC-147834-LHQ2R	Nuvia Ltd	25/05/2017	<ul style="list-style-type: none"> • Confirmation of the status of the study's Microdata Release Panel approval and confirmation of renewed Approved Researcher accreditation for one individual. • Including a special condition that the applicant must make suitable fair processing information available via a public facing website, including details of how to opt out of the study and a statement that opting out will not affect employment status, in order to meet the patient notification requirement of their section 251 support and the minimum privacy notice criteria set out by NHS Digital. This should take place as soon as reasonably possible, within a maximum of four weeks, and no further data will be disseminated until this has been met. It was advised that the applicant should consider informing trade unions once updated fair processing information is available via a website. 	IGARD Chair	IGARD Chair	N/A
NIC-13925-Q7R2D	IMS Health Ltd	08/06/2017	<ul style="list-style-type: none"> • Clarification of whether the proposed use of data is in line with the Research Ethics approval. • The applicant should provide a clearer justification for the number of data years requested, or limit the number of data years to a rolling 10 years. 	IGARD quorum	Director of Data Dissemination following discussion with IGARD Chair	This application was circulated to IGARD 27/06/17 for review but following email discussion the conditions were signed off by the

						Director of Data Dissemination following discussion with IGARD Chair 10/07/17.
--	--	--	--	--	--	---

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

- NIC-17875-X7K1V University of Bristol
- NIC-324220-P6W9Y Queen Mary University of London