Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 25 May 2017

Members: Sarah Baalham, Joanne Bailey, Chris Carrigan, Jon Fistein, Kirsty Irvine, Debby Lennard (items 1 – 2.5), James Wilson (items 1 – 2.10)

In attendance: Dave Cronin, Jen Donald, Frances Hancox, Louise Hill, Terry Hill, Dickie Langley, Stuart Richardson, Joanne Treddenick (observer)

Apologies: Anomika Bedi, Nicola Fear, Eve Sariyiannidou

1	**Declaration of interests** James Wilson declared a potential conflict of interest in the University College London application (NIC-37191-P5S9S) due to his employment by that organisation. **Review of previous minutes and actions** The minutes of the 18 May 2017 IGARD meeting were reviewed and agreed as an accurate record of the meeting, subject to a minor change. Action updates were provided (see Appendix A). **Out of committee recommendations** An out of committee report was received (see Appendix B). IGARD noted that a significant number of applications submitted to this meeting had not been through the standard Pre-IGARD checking process, and expressed their hope that this would be a one-off occurrence due to NHS Digital staffing difficulties.
2 **2.1**	**Data applications** <u>Institute of Occupational Medicine - Cohort mortality study of workers occupational exposed to lead in Great Britain (Presenter: Jen Donald) NIC-149506-6C4GX</u> **Application:** This application to amend an existing agreement had previously been considered at the 11 May 2017 IGARD meeting, when IGARD had deferred making a recommendation. The application had now been updated to address the points raised, confirmation had been provided that the applicant's Approved Researcher accreditation had been extended and IGARD were informed that the data sharing contract between the Institute of Occupational Medicine (IOM) and the International Agency for Research on Cancer (IARC) had been amended. **Discussion:** IGARD noted the updated data sharing contract with IARC and suggested that it would be helpful to update this to include the date of signature, due to a statement that this was active from the date of signature. There was a discussion about the requirement within the data sharing contract for IARC to provide the IOM with all necessary evidence with respect to its storage and usage of the data, to ensure that the terms of the agreement were being abided by. IGARD suggested that section five of the application should be updated to include that if IARC did not respond to such a request in a timely manner, then the IOM should inform NHS Digital of this.

	Outcome: Recommendation to approve. Section five of the application should be amended to include a requirement that if IARC does not respond to a request made for necessary evidence to ensure that the terms of their data sharing agreement with IOM are being abided by within a timely manner, then IOM is responsible to inform NHS Digital of this. IGARD suggested that the IOM – IARC data sharing agreement should be updated to include the date of signature.
2.2	Device Access UK Ltd (Presenter: Jen Donald) NIC-05429-H7X6R This application was withdrawn shortly prior to the meeting, at the request of the presenter.
2.3	University of Oxford - advice on consent (Presenter: Jen Donald) NIC-392669-T1F8B **Application:** This application, which related to a cohort of patients who underwent coronary artery bypass grafting at the John Radcliffe hospital, was presented to IGARD for advice on the consent materials only. It was noted that two of the three studies within the application had completed recruitment, while recruitment was ongoing for the third study; recruitment for the three studies had begun in 2004, 2005 and 2011 respectively. **Discussion:** IGARD discussed the consent materials for the two older studies. On balance it was agreed that although these did not describe future data sharing as clearly as would be expected in more recent consent materials, there were no statements that would be expected to prevent the sharing and use of data for this purpose and that it might therefore be appropriate to provide participants with updated fair processing information via a newsletter, as well as updating the study website, as long as this also provided a straightforward means for individuals to withdraw their consent from the study if they wished to do so. In general IGARD agreed with the queries about the study consent that had previously been raised by NHS Digital's IG ISA staff, and suggested that the applicant should work to address these points. There was a discussion about possible ways forward given the concerns about the consent material, and IGARD suggested that the applicant might wish to consider undertaking list cleaning to receive updated address details for living participants prior to issuing a newsletter that could provide clear information about the proposed data usage as well as offering the opportunity to withdraw consent. IGARD then discussed the consent materials for the third study, for which recruitment was still underway. IGARD agreed that these seemed to offer clearer information than the materials for the other two studies, but some concerns were raised that the use of Office for National Statistics (ONS) mortality data was not sufficiently explained. It was also suggested that information about how individuals could in future withdraw their consent could have been presented more clearly with contact information. IGARD suggested that the applicant should work with NHS Digital IG staff to update their consent materials in a timely manner for their ongoing recruitment, and update the study website to provide clearer fair processing information particularly for those individuals who had already consented using the existing materials. IGARD queried a reference to Jersey in a supporting document and requested clarification of whether NHS Digital held healthcare data for Jersey, and if so whether this was part of the data requested in this application. **Outcome:** IGARD advised that they were agreement with the comments and queries raised by IG ISA in relation to these consent materials and suggested that the applicant should respond to those queries. IGARD suggested that for the two studies that had completed recruitment, the applicant might

	wish to consider undertaking a list cleaning exercise to receive fact of death and updated address details in order to send living participants a newsletter with clear information about the proposed use of data and an easy, accessible way for individuals to withdraw their consent if they wish to do so. In addition IGARD advised that for the study with ongoing recruitment, the study should work with NHS Digital IG staff to update their consent material wording in a timely manner and that this should include making it clearer how participants can get in touch if they wish to withdraw their consent. For the participants who had already consented for that study, IGARD suggested more fair processing information should be provided via the study website. IGARD provided this advice without prejudice to the consideration of any future application.
2.4	<u>University of Nottingham - Prospective Study in the Lung Endpoints (Presenter: Dave Cronin) NIC-160361-NDZKG</u> **Application:** This application was to extend the applicant's previous data sharing agreement in order to allow them to retain the data previously received, with no additional data to be disseminated at this point in time. IGARD were informed that the applicant had previously shared data with GlaxoSmithKline in a way that NHS Digital considered a technical breach of their data sharing agreement, and that an initial informal investigation into this had taken place. No data sharing with GlaxoSmithKline would be permitted under the current data sharing agreement with NHS Digital; confirmation would be required that GlaxoSmithKline had securely destroyed the data that was previously shared with them. Work was underway to review the security assurances for GlaxoSmithKline in order that they could formally act as a data processor in future but this assurance process had not yet been completed. A short term (three month) extension was therefore requested to cover until a future application could be made to include this data processor, as at present the applicant's previous data sharing agreement had lapsed. **Discussion:** IGARD queried the steps taken by NHS Digital in the event of a suspected breach of data sharing agreement, and what criteria were used to determine whether something was considered a technical breach or a more serious breach. It was agreed it would be helpful for IGARD to have sight of information about the organisational policies around this type of technical breach. IGARD were informed that at present an informal investigation had taken place, and that a formal data sharing audit was planned. IGARD queried how information about this technical breach would be made publicly available, as it was noted that this was not described within section five of the application that would be reflected on the release register; IGARD urged NHS Digital to consider ways to improve transparency around this type of data sharing agreement breach. In addition IGARD suggested that NHS Digital should carry out an audit as soon as reasonably possible, and noted that when a renewal application was submitted they would expect this to include an update on the findings from this audit. IGARD expressed their support for the approach taken to extend the data sharing agreement given that the previous agreement had lapsed. There was a discussion of the requirement for GlaxoSmithKline to destroy the data previously shared with them by the University of Nottingham, and IGARD agreed that the application should be amended to include a requirement for this to be confirmed within four weeks. IGARD queried a statement in the application that the data previously released had contained identifiable fields that were not clearly justified in the current application. It was explained that this was a legacy issue from the patient tracking services that had previously been offered, which had not taken the same data minimisation steps that would be offered now, and it was expected this would need to be considered further when a future application was submitted for more data to be disseminated. Furthermore a reference to outputs being suspended was queried and IGARD asked for this wording to be amended to be clear that this referred to the dissemination of data from NHS Digital being suspended, rather than the applicant's outputs

	being suspended. IGARD noted that a quotation from the applicant included in the application about donations from now deceased participants was unhelpful and suggested that this should be removed from future versions of the application. A query was raised about a statement that this work was 'sponsored' by the University of Nottingham and it was agreed this should be clarified. In addition IGARD queried a reference to a previous IGARD recommendation in the application and asked for this to be amended to clarify that this in fact referred to the version of DAAG that had existed in 2012. **Outcome:** Recommendation to approve. A reference to halting outputs should be amended to be clear this refers to halting the dissemination of data from NHS Digital. The statement that the study is 'sponsored' by the University of Nottingham should be clarified. The special condition requiring confirmation around data previously shared with GlaxoSmithKline should be updated to include that NHS Digital should receive confirmation within four weeks that GlaxoSmithKline have securely destroyed this data. A reference to IGARD should be corrected to be clear this instead refers to the DAAG that existed in 2012. IGARD noted the particular circumstances around this application as NHS Digital considered that a technical breach had occurred, and advised that NHS Digital should consider how to increase transparency around this type of breach. In addition IGARD encouraged NHS Digital to carry out a data sharing audit in a timely manner. It was agreed that when a renewal application was submitted within three months this should include an update on whether a data sharing audit had been completed and its findings. **Action**: Dave Cronin to provide information to IGARD regarding the NHS Digital policy on how different types of data sharing agreement breaches are classified and handled.
2.5	<u>University College London - Medical Research Council Clinical Trials Unit RADICALS Trial (Presenter: Dave Cronin) NIC-37191-P5S9S</u> **Application:** This application requested patient tracking services for a cohort of participants across two clinical trials. IGARD were informed that following application submission, section five of the application had been updated to indicate that the standard ONS terms and conditions would apply. **Discussion:** IGARD queried a statement within the application abstract that indicated an update to the consent wording would provide a legal basis for data to be disseminated under the Statistics and Registration Service Act 2007, as section three of the application did not list this Act as a legal basis to disseminate data. IGARD noted that the applicant would provide a number of identifiers to NHS Digital including postcode, but that the fair processing material available online did not appear to cover the use of postcode. It was agreed that the online information should be updated promptly to include this. In addition IGARD queried the description of data retention currently provided online, and suggested that this should also be updated to incorporate the information about planned data retention provided within the application. There was a discussion of the applicant's security assurances, and IGARD queried the statement within the application that the applicant had begun version 14 of the IG Toolkit in June 2016 but apparently not yet submitted. In addition a reference to the NHS Digital security consultant confirming arrangements was queried and IGARD suggested that in future it would be helpful to be clear that this was due to the use of ONS data. IGARD noted that they had previously queried the standard special condition wording around the need for applicants to inform NHS Digital if their version 14 IG Toolkit score was not reviewed as satisfactory, and it was agreed the IGARD Chair would raise this within NHS Digital.

	There was a discussion of the role of the Independent Data Monitoring Committee, as it was unclear from the wording in section five of the application whether this committee would have sight of record level data and if so, whether all committee members were substantive employees of University College London or what other contractual arrangements were in place. It was confirmed that while the committee would have sight of other record level data from the trial in order to carry out their important monitoring function, this would not include any record level data supplied by NHS Digital. It was therefore agreed the application wording should be updated to confirm that regarding NHS Digital data, the committee would only receive aggregated data with small numbers appropriately suppressed. **Outcome:** Recommendation to approve. The legal basis to disseminate data should be amended within the application to include the Statistics and Registration Service Act 2007. A special condition should be added requiring the applicant should update information on their website, within eight weeks, about what data will be shared with NHS Digital to be clear this includes postcode, and should provide clearer information about data retention in line with the information given in the patient information sheet as well as within this application. The application should be amended to remove a reference to the applicant having started version 14 of the IG Toolkit, and should state the legal basis for NHS Digital to receive identifiers. Section five should also be updated to confirm that only substantive employees of UCL will access record level data or aggregated data containing small numbers, and to state that the Independent Data Monitoring Committee will only receive aggregated data with small numbers suppressed. It was noted that section five of the application had been updated to include that the standard ONS Terms and Conditions would apply. **Action**: IGARD Chair to contact Garry Coleman regarding the special condition wording around version 14 IG Toolkit review, and the associated risk of requiring applicants to report back to NHS Digital.
2.6	<u>Heywood, Middleton and Rochdale CCG (Presenter: Stuart Richardson) NIC-90049-D5S8M</u> **Application:** This application was to amend an existing agreement to add MSD Healthcare Services as a data processor for the purpose of risk stratification, for the CCG itself to receive a flow of pseudonymised Secondary Uses Service (SUS) and local flows data for the purpose of invoice validation, and to extend the dataset period of existing data flows. IGARD were informed of an error on the data flow diagram as this did not reflect the use of a pseudonymisation tool. It was noted that some of the points raised at the previous IGARD meeting had not yet been addressed in this version of the template. **Discussion:** IGARD queried the legal status of MSD Healthcare Services as an organisation, as it was thought that this organisation was either a trading name for or otherwise linked to Merck. It was agreed that more information was needed about this and about how access to data would be limited within the organisation, including confirmation that data would not be accessed from overseas. There was a discussion of the missing box on the data flow diagram. IGARD queried the use of pseudonymisation tools, and whether it might be possible to pseudonymise data closer to its source to reduce the flow of identifiable data between different organisations. The table of data requested was discussed and IGARD asked for this to more clearly indicate which data flows would be new due to the additional purpose of invoice validation. IGARD noted that in some web browsers, the CCG's privacy notice webpage showed a warning about security certificates and IGARD advised that the applicant should ensure their privacy notice was securely accessible to the general public.

	IGARD noted that the application stated MSD Healthcare Services would use this data to develop and test new risk stratification algorithms, and queried whether this purpose could be considered commercial. In addition IGARD queried whether it was appropriate to release data under the section 251 support for risk stratification when it would be used for this type of algorithm testing. Confirmation was requested of whether this provision of data would be consistent with the approach taken by NHS Digital to disseminating data for software development purposes. There was a brief discussion of the national test bed programme that this data would be used for, and IGARD noted that other organisations such as Verily Life Sciences were also involved in this programme. It was agreed that section five of the application should include a commitment that the data provided under this agreement would not be shared with other organisations involved in the programme such as Verily. A query was raised about the information sharing protocol provided, as this seemed to state that it would be due for review in 2015. Confirmation was requested that the copy provided was the current version. **Outcome:** Recommendation deferred: • Clarification regarding the Test Bed Programme and whether this use of data is covered by the section 251 support for risk stratification, with confirmation that the use of live data for this purpose is consistent with the general approach taken by NHS Digital to the use of data for software development. • Confirmation that given the use of data to develop algorithms, NHS Digital are content that this use of data is not considered commercial. • Further information was requested about the legal status of MSD Healthcare Services and how data usage would be limited within that organisation, with confirmation that data will not be accessed from overseas. • Confirmation that the version of the Information Sharing Protocol provided is the current version, given that this refers to a planned review in 2015. • Further information about the use of pseudonymisation at source tools and whether it might be practical to pseudonymise data at an earlier stage to reduce the sharing of identifiable data. The table of data requested should be updated to more clearly explain the new data flows for invoice validation. Section five of the application should be amended to explicitly state that data will not be shared with Verily Life Sciences under this agreement. The data flow diagram would be updated to include the use of a pseudonymisation tool within general practices. A reference in section five to Annex A of the DSA should be clarified. It was noted that the privacy notice link provided seemed to result in a warning about security certificates, and that the applicant should ensure this information was securely accessible to the general public.
2.7	<u>University of Sheffield - An Evaluation of Alcohol Treatment Centres: Implications for Service Delivery, Patient Benefit and Harm Reduction (Presenter: Dickie Langley) NIC-29100-R2S2F</u> **Application:** This application requested pseudonymised HES data across a number of cities to support research into alcohol intoxication management services. IGARD were informed that since the application had been submitted, the applicant's version 14 IG Toolkit submission had now been reviewed as satisfactory and the application would be updated to reflect this. **Discussion:** IGARD acknowledged the potential benefits to the healthcare system that could be achieved through this work. A query was raised about the controls in place around access to data. It was agreed section five should be updated to include a commitment that only substantive employees of the

	University of Sheffield would have access to record level data, and that any information shared outside that organisation could only be aggregated data with small numbers appropriately suppressed. In addition confirmation should be included that no attempts would be made to reidentify the data. There was a discussion about the importance of fair processing, given that the EU General Data Protection Regulation would come into force within one year. It was agreed that IGARD would offer standard advice to applicants in receipt of pseudonymised data. A query was raised about the number of cities included in this research, as this seemed to be described inconsistently within the application. A further query was raised about the data minimisation efforts, as it was noted that HES Admitted Patient Care data would be limited to alcohol related incidents; it was confirmed the same minimisation could not be applied to HES A&E data due to the requirements of the research. A reference in section five of the application to data being anonymised was queried and IGARD suggested this should be amended to refer to pseudonymisation. **Outcome:** Recommendation to approve Section five should be amended to include a statement that only substantive employees of the University of Sheffield will have access to record level data, and that no attempts will be made to reidentify data. This section should also be amended to state that no record level data will be shared outside the substantive employees referred to, and that all outputs shared with third parties will only contain aggregated data with small numbers appropriately suppressed. A reference to data being anonymised should be amended to pseudonymised. It was noted the application would be amended to reflect the applicant's version 14 IG Toolkit score. It was agreed that the total number of cities should be confirmed as this was described inconsistently within the application. IGARD advised that the applicant should consider updating their DPA registration to include processing data about patients or health service users. As a result of this application IGARD would like to draw the applicant's attention to the to the importance of the accessibility and clarity of their Privacy Notice and the absence of any reference to the absence of any reference to using data from NHS Digital in this. The applicant is advised to review their notice against the ICO's Privacy Notices Code of Practice to ensure it reflects best practice standards and in the interests of transparency, update their notice as soon as possible. The applicant will be expected to demonstrate progress against this recommendation in any audit undertaken and completion of the requirement for any renewal / new application for data. The EU 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, and IGARD would remind applicants that this will come into force in May 2018.
2.8	<u>University of Exeter - A Spatial Microsimulation model of Comorbidity (Presenter: Dickie Langley) NIC-03716-R3W8Q</u> **Application:** This application requested a tabulation of aggregated data, including small numbers, for use in a project funded by the Economic and Social Research Council (ESRC) Secondary Data Analysis Initiative around methods of analysing healthcare data. IGARD were informed that section three of the application did not currently list the full legal basis for dissemination under the Health and Social Care Act 2012, and that this would be corrected. **Discussion:** IGARD discussed the potential benefits of this methodological research and agreed that this seemed to be in line with the requirements of the Care Act 2014. However it was agreed that the application wording should be amended to more clearly describe the

	potential healthcare benefits if the accuracy of this method could be demonstrated, as this could potentially reduce the need for other flows of patient data in future. It was noted that the applicant's DPA registration referred to the use of data for health research, but did not specify processing data about patients and IGARD suggested that the applicant should consider updating this. **Outcome:** Recommendation to approve. The application should be amended to more clearly describe the possible benefit in demonstrating the accuracy of this model if it could reduce the need for flows of other patient data in future. IGARD advised that the applicant should consider updating their DPA registration to include processing data about patients or health service users. As a result of this application IGARD would like to draw the applicant's attention to the to the importance of the accessibility and clarity of their Privacy Notice and the absence of any reference to the absence to any reference to collecting data from NHS Digital for the purposes described in the application, and the type of data requested in this. The applicant is advised to review their notice against the ICO's Privacy Notices Code of Practice to ensure it reflects best practice standards and in the interests of transparency, update their notice as soon as possible. The applicant will be expected to demonstrate progress against this recommendation in any audit undertaken and completion of the requirement for any renewal / new application for data. The EU 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, and IGARD would remind applicants that this will come into force in May 2018.
2.9	<u>Ieso Digital Health - IAPT data for clinical and cost-effectiveness analysis (Presenter: Dickie Langley and Kate Croft) NIC-76652-B3F1D</u> **Application:** This new application requested pseudonymised Improving Access to Psychological Therapy (IAPT) data. **Discussion:** There was a discussion of the amount of data requested, and whether it would be proportionate to provide national data for this type of benchmarking analysis. Further information was requested about the geographical base of Ieso, with a clear justification for why this amount of data would be required for comparison purposes. Concerns were raised about the purpose of this work, as it appeared that this was a commercial purpose with the resultant analysis potentially being used to promote the applicant's services. IGARD did not consider that this purpose as currently described would be consistent with the requirements of the Care Act 2014. There was a brief discussion of the applicant's fair processing information and IGARD advised that in the interests of transparency, more information about their use of healthcare data and in particular mental health data ought to be made available online for the general public. IGARD noted the involvement of the York Health Economics Consortium in this work, who were described as having a consulting role. It was suggested that the applicant might wish to consider commissioning an independent organisation to carry out the data analysis and evaluation work on their behalf, to help ensure academic rigour and reduce any potential appearance of bias in the outputs and in how the data would then be used to benefit the healthcare system. **Outcome:** Not recommended for approval. IGARD considered that the purpose and data processing described appeared to be for a commercial purpose and that this did not appear to be in line with the requirements of the Care

	Act 2014. It was suggested that one way forward might be for the applicant organisation to commission an independent organisation to carry out an evaluation on their behalf. Further information would be required about the geographical base of Ieso with a clearer justification for why national data is required for the purpose of benchmarking. As a result of this application IGARD would like to draw the applicant's attention to the to the importance of the accessibility and clarity of their Privacy Notice. The applicant is advised to review their notice against the ICO's Privacy Notices Code of Practice to ensure it reflects best practice standards and in the interests of transparency, update their notice as soon as possible. The EU 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, and IGARD would remind applicants that this will come into force in May 2018.
2.10	<u>Nuvia Ltd – Ex-employees of the Atomic Weapons Research Establishment (Presenter: Dickie Langley) NIC-147756-SMGHS</u> **Application:** This renewal and extension application requested further MRIS data about NHS entries and exits, cancer registration and ONS mortality data (including cause of death) for a specific cohort. Data would be used to analyse mortality and cancer morbidity in the employees of the Atomic Weapons Establishment (AWE) at Aldermaston, with section 251 support providing the legal basis. **Discussion:** IGARD acknowledged the potential significance of this study and the important benefits that could potentially arise from this. The applicant's fair processing materials were discussed and IGARD raised concerns that these were only available via an internal intranet page, given that the application indicated only a very small percentage of the cohort were still employees at the AWE. It was agreed that clear fair processing information would need to be made available, as soon as reasonably possible, on a public facing website and that this should include clear information about how individuals could opt out if they wished to do so. In addition IGARD advised that once this information was available online, trade unions should be made aware of this and provided with the website link. There was a discussion about the role of Public Health England as a data controller, and it was confirmed that while they would act as data controller they would not have direct access to the data shared under this agreement. IGARD discussed the special conditions included in this application, and it was agreed that section five should be updated to indicate that the standard ONS terms and conditions would apply. The special condition around version 14 IG Toolkit review was discussed, and it was noted that an action had already been raised for the IGARD Chair to discuss this with NHS Digital. Confirmation was requested of whether the study Microdata Release Panel approval had been extended, as this was unclear from the documentation provided. In addition it was noted that the Approved Researcher accreditation for one member of staff appeared to have expired and confirmation would be needed that this had been renewed. IGARD queried a reference in the application to sharing data in 'anonymised form' with collaborators following permission from NHS Digital. It was agreed that this statement should either be more clearly explained, or removed from the application. In addition IGARD queried the cohort size as this and the number of opt-outs seemed to have been described inconsistently between this application and the section 251 documentation. There was a discussion about the proposed linkage to radiation exposure data and it was agreed the application wording should be updated to be consistent with the flows shown on the data flow diagram. In addition it was agreed that section five should be amended to be clear that only the named Approved Researchers would have access to the record level data.

There was a discussion about the process to apply type two objections, and IGARD noted that the application indicated that when current workers were recently updated on the use of data none had chosen to opt out. It was confirmed that type two objections would be applied to this flow of data given the use of section 251 as a legal basis, and that the application of opt outs was something that would normally be considered by HRA CAG as part of the section 251 process.

IGARD queried a statement that the data disseminated would be the 'latest data available as at time of approval'. It was clarified that this was due to the nature of the dataset, as this was continually updated and the data disseminated would always be the most recent that was available at that time.

Outcome: Recommendation to approve, subject to condition:

- 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, 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 the website.

A reference to sharing data in anonymised form with collaborators should be clarified or removed. The cohort size should be clarified as this was described inconsistently within the application. Section five should be amended to include a statement that the standard ONS T&C apply.
References to linking to radiation exposure data should be clarified for consistence with the data flows show within the diagram. A statement that data will only be visible to staff with a need to see it should be updated to be clear this will only be individuals with Approved Research accreditation. The special condition wording around the need for version 14 IG Toolkit scores to be reviewed should be updated.
IGARD advised that Nuvia should consider updating their DPA registration wording to be clear that the use of data for research is not solely limited to survey respondents, and to describe processing data about patients or health service users.

2.11 Nuvia Ltd - UKAEA Mortality Study (Presenter: Dickie Langley) NIC-147834-LHQ2R

Application: It was noted that this application was very similar to the previous Nuvia Ltd application (NIC-147756-SMGHS) but focused on a cohort from the UK Atomic Energy Authority (UKAEA).

Discussion: IGARD reiterated a number of the points raised in relation to the previous application, including the need to improve the fair processing information made available to participants. It was agreed that as this study involved a larger proportion of current employees, the fair processing information should also clearly state that choosing to withdraw from the study would not have any impact on an individual's employment.

Outcome: Recommendation to approve, subject to conditions:

- 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. A reference to sharing data in anonymised form with collaborators should be clarified or removed. Section five should be amended to include a statement that the standard ONS T&C apply. References to linking to radiation exposure data should be clarified for consistence with the data flows show within the diagram. A statement that data will only be visible to staff with a need to see it should be updated to be clear this will only be individuals with Approved Research accreditation. The special condition wording around the need for version 14 IG Toolkit scores to be reviewed should be updated. IGARD advised that Nuvia should consider updating their DPA registration wording to be clear that the use of data for research is not solely limited to survey respondents, and to describe processing data about patients or health service users.
2.12	<u>NHS Digital - National Bowel Cancer Audit (Presenter: Dickie Langley) NIC-376603-K2J9R</u> **Application:** This application had previously been discussed at the 11 May 2017 meeting when IGARD deferred making a recommendation. Confirmation had since been sought from HRA CAG that the audit's section 251 support covered the Welsh data flows described in this application. **Discussion:** IGARD noted the information they had received from the IG Advisor on her review of the section 251 supporting documents provided for this application. There was a discussion about the various documents provided and IGARD agreed that while it was disappointing that their previous query regarding which application version CAG had reviewed had not been directly answered, a thorough review of the documentation did on balance seem to evidence that the section 251 support covered Welsh data flows. In particular it was noted that both the annual review application, and the amendment outcome letter from CAG in 2015, specifically mentioned PEDW or data about patients in Wales. IGARD noted that this recommendation was based on the assumption made by NHS Digital IG staff to confirm that a legal basis was in place under section 251 support. **Outcome:** Recommendation to approve.
3	**Any other business** There was a brief discussion about data flow diagrams submitted with Data Services for Commissioners applications.

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. 25/05/17: Ongoing.	Open
23/03/17	To provide additional information about the application checks made by the Pre-IGARD process	Gaynor Dalton	06/04/17: Ongoing. It was anticipated a response would be provided at the following IGARD meeting.	Open

	before applications are submitted to an IGARD meeting.		13/04/17: A verbal update was given on the Pre-IGARD process and it was agreed that it would be helpful on both sides to develop a Pre-IGARD checklist to define what checks would be carried out as standard for each application before reaching IGARD. 27/04/17: Gaynor offered to provide a marked up application to demonstrate the types of comments raised at Pre-IGARD, but IGARD felt that this could be potentially prejudicial to the consideration of that application. 04/05/17: Ongoing. This had been discussed as part of the morning educational session. 18/05/17: IGARD received a verbal update about the increased involvement of the IG Advisor in Pre-IGARD and about the role of Operational IG staff within DARS. There was a suggestion that the Deputy Caldicott Guardian could also attend Pre-IGARD. IGARD advised that it would still be helpful to have sight of a checklist to confirm what items should be checked prior to an application reaching an IGARD meeting. 25/05/17: Ongoing.	
23/03/17	To provide a response to previously raised IGARD queries about indemnity.	IGARD Secretariat	06/04/17: An update had been provided and the action remained open. 13/04/17: This was ongoing within NHS Digital. 25/05/17: Ongoing.	Open
30/03/17	To contact the NHS Digital Caldicott Guardian regarding how NHS Digital handles applications from organisations whose IG Toolkit has been reviewed as satisfactory with an improvement plan.	IGARD Chair	06/04/17: This had been raised but a response had not yet been received. 18/05/17: IGARD noted a verbal update provided about upcoming changes to the IG Toolkit and how this would be reviewed. It was agreed further clarity was still required about how this issue would be handled with existing applications until the IG Toolkit changes came into effect. 25/05/17: Ongoing.	Open
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	25/05/17: 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.	IGARD Chair	18/05/17: Ongoing. It was agreed this would be discussed with the Deputy Caldicott Guardian. 25/05/17: 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.	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	25/05/17: Ongoing.	Open
25/05/17	Dave Cronin to provide information to IGARD regarding the NHS Digital policy on how different types of data sharing agreement breaches are classified and handled.	Dave Cronin		Open
25/05/17	IGARD Chair to contact Garry Coleman regarding the special condition wording around version 14 IG Toolkit review, and the associated risk of requiring applicants to report back to NHS Digital.	IGARD Chair		Open

Appendix B: Out of committee report (as of 19/05/17)

The following application conditions have been signed off by IGARD:

- NIC-41632 Camden CCG (SA03-CON-NEL) *(Considered at 1st November 2016 DAAG meeting)*

The following application conditions have been signed off by the IGARD Chair:

- Group Application for 5 CCGs (GA06-CON-NEL) *(Considered at 15th November 2016 DAAG meeting)*
- NIC- 55709 Waltham Forest CCG (SA09-CON-NEL) *(Considered at 1st November 2016 DAAG meeting)*