Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 7 June 2018

Members: Chris Carrigan, Nicola Fear, Kirsty Irvine (Chair), Eve Sariyiannidou.

In attendance: Dave Cronin, Arjun Dhillon, Louise Dunn, Rachel Farrand, James Smith (Observer), Joanne Treddenick, Kimberley Watson, Aaron White, Vicki Williams.

Apologies: Sarah Baalham, Joanne Bailey, Anomika Bedi, Jon Fistein.

1	**Declaration of interests** Nicola Fear noted a personal and professional link to NIC-389134-S8L1C University of Oxford and would not be part of the discussion and would not remain in the meeting for the discussion of that application. **Review of previous minutes and actions** The minutes of the 24 May 2018 IGARD meeting were reviewed by IGARD and agreed as an accurate record of the meeting.
2	**Data applications**
2.1	University of Oxford: The Million Women Study (Presenter: Dave Cronin) NIC-389134-S8L1C **Application:** This was an amendment application to permit the current monthly flow of identifiable data for the purpose of the Million Women Study to make data from the dataset (including data supplied by NHS Digital and its predecessor under the current Agreement) available to bona fide researchers to use for medical research subject to separate approvals. The Million Women Study is a national study of women's health, involving more than one million UK women aged 50 and over and is a collaborative project between Cancer Research UK and the NHS, with additional funding from the Medical Research Council and the Health & Safety Executive which aims to answer many outstanding questions about the factors affecting women's health in this age group. **Discussion:** IGARD noted the importance of the study and that they were not quorate to make a recommendation, however would provide detailed comment. IGARD noted that the application had previously been presented to its predecessor (DAAG) for advice and that the advice previously given was still relevant and issues raised had not been adequately addressed within the application including the relevant legal basis and evidence of ethics approval for the revised study protocol. NHS Digital noted that the study was about general women's health but the original study focused primarily on breast screening and that the applicant had applied for updated Research Ethics Committee (REC) approval based on the new protocol issued to the study participants. IGARD suggested that evidence be provided that the revised study protocol, which covers a wide range of purposes beyond the original study purpose, had received ethics approval. IGARD noted that the applicant should update their website to clearly outline to all study participants the current processing and purpose of the study since this was not currently listed. IGARD noted that evidence should be provided how the applicant had made a consistent effort to revise newsletters disseminated to study participants and the newsletters should clearly reflect the wider research purpose and processing activities undertaken. IGARD noted that the original consent had stated 'women's health' but that the wording was not granular and that section 5 of the application be updated to explicitly state that there was no

	restriction to use the data more widely and to explain how the purpose of the Million Women's Trial had expanded. IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested. IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5b of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement. IGARD noted the new fair processing notice requirements and that new standard wording be used within the fair processing section: "All data required by the Data Controller is considered as personal data under the General Data Protection Regulation (GDPR). All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at the latest within one month." IGARD queried access by third parties and suggested that the process agreement be clarified by revising the wording in section 5 of the application and clearly stating the method agreed between the University of Oxford and NHS Digital which would enable access by researchers to record level data held by the applicant. **Outcome:** IGARD were unable to make a recommendation as there was not a quorum of members present. The following comments were made: 1. Provide evidence that the revised study protocol which covers a wider range of purposes than the original purpose has received ethics approval 2. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 3. The Fair Processing section to be amended to include the new standard wording: "All data required by the Data Controller under this application is considered personal data under the General Data Protection Regulation (GDPR). All Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at the latest within one month." 4. The applicant's website be updated to clearly outline to study participants the current processing and purpose of the study. 5. To be explicit within section 5 of the application how the purpose of the million women's trial has expanded. 6. To include in section 5 the revised wording which reflects the method agreed between the University of Oxford and NHS Digital which would enable access by researchers to record lever data held by the applicant. 7. Confirmation within section 5b of the application that the applicant will not link the data further and the only data linkages are those permitted under this application. 8. To provide evidence that a consistent effort has been undertaken to revise newsletters sent to participants which accurately reflect the wider research purpose and the processing activities.

2.2	Office for National Statistics (ONS): HDIS access to pseudonymised Hospital Episode Statistics (HES) to support feasibility research and familiarisation in advance of seeking identifiable extracts under the Statistics and Registration Services Act 2007 (Presenter: Dave Cronin) NIC-177068-M1P0L **Application:** This was a new application for ONS to access HES Data Interrogation Service (HDIS), hosted and audited by NHS Digital. ONS are working with NHS Digital's analytical experts to better understand HES data and whether it will be fit for the statistical purposes to which ONS wants to use it and remote access to pseudonymised HES data will support this process. **Discussion:** IGARD thanked NHS Digital for the briefing note provided with the application and queried the references to the Statistics & Registrations Services Act 2007. NHS Digital explained the various sections outlined (section 45a and section 45c) within the application and the information governance structure in place within ONS. IGARD noted for transparency that section 5 of the application be updated to clearly distinguish what is currently being undertaken with the current disseminations and what will be undertaken in the future, and especially because the future work outlined in the application may be viewed by the public as another big national data repository in addition to NHS Digital. IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested. IGARD also noted that Public Health England (PHE) had recently undertaken a cancer peer review and suggested that the applicant may wish to speak to PHE. **Outcome:** recommendation to approve subject to the following condition: 1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. The following amendment was requested: 1. To distinguish within section 5 between what is currently being undertaken with the current dissemination of data and what may be done in future. The following advice was given: 1. IGARD suggested the applicant speak with Public Health England with regard to cancer peer review work already being undertaken It was agreed the condition would be approved OOC by IGARD Members
2.3	University Hospitals Bristol NHS Foundation Trust: Hospital Episodes Statistics (HES) and Office for National Statistics (ONS) data for the AIRWAYS-2 cluster randomised trial (Presenter: Louise Dunn) NIC-35562-V6G5W **Application:** This was a new application from South Western Ambulance Service NHS Foundation Trust as the Data Controller requesting a one of linked HES-ONS extract linked to their recruited cohort of approximately 4,000 with a request to receive data for each patient for the 6 month period after their cardiac arrest. HES/ONS data provided will be linked to trial data collected by the Clinical Trials and Evaluation Unit at University Hospitals Bristol NHS Foundation Trust who will share the linked data with health economists at the Nuffield

	Department of Population Health at the University of Oxford who will conduct an economic evaluation of the study. This a National Institute for Health Research (NIHR) funded study. NHS Digital noted that the IG Advisor to IGARD had confirmed that the legal basis to disseminate the data should be s261(7). **Discussion:** IGARD noted this was a NIHR funded application and that it should be clear within the abstract that this application was not part of the current NIHR funded trial. IGARD also noted that the advice to amend the legal basis to s261(7) within section 3 of the application as the legal basis to disseminate data. IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested. IGARD noted that supporting document 1 provided was a collaboration agreement and queried why the collaborators listed in this document were not listed as Data Controllers. NHS Digital noted that the applicant had stated that South Western Ambulance Service NHS Foundation Trust were the sole Data Controller however IGARD suggested that since the collaboration document provided stated that the project was shared equally between collaborators that clarification be sought. IGARD noted that the collaborators were not accessing the data and that a clear explanation should be provided in section of the roles and responsibilities of the collaborators outlined in supporting document 1 and the application and clarifying the legal basis for each of the collaborators to receive and process the data. IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5b of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement. IGARD queried if the individuals accessing the data were substantive employees with the appropriate honorary contracts in place and suggested that the appropriate clause was included that the substantive employer of the individuals under the honorary contract would take appropriate action in the event of a breach and that a copy of the honorary contract(s) be provided to NHS Digital. IGARD noted that previously those patients deceased at the scene were not included in the study, but that under this application those patients deceased upon arrival at hospital following a cardiac arrest would be included within the study, along with those who survived at hospital but that it be clearer within section 5 and as outlined in the data flow diagram provided. IGARD also suggested that references to the University of Oxford throughout the application be updated to refer to the Nuffield Department of Population Health as appropriate. **Outcome:** recommendation to defer, pending: 1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. Giving a clear explanation within section 5 of the application the roles and responsibilities of the collaborators outlined within the application and the legal basis for them to receive and process data.

	3. Clarifying why the organisations listed in supporting document 1 are not listed as joint Data Controllers. 4. Confirmation within section 5b of the application that the applicant will not link the data further and the only data linkages are those permitted under this application. 5. Confirmation within section 5 of the application that the individuals accessing the data are substantive employees with the appropriate honorary contract in place which will include a clause that the substantive employer of the person under the honorary contract will take appropriate action in the event of a breach and that the honorary contract will need to be in place and a copy be provided. 6. To confirm within section 5 that those patients who are deceased upon arrival at hospital are included within the study, as outlined in the data flow diagram. 7. To include the legal basis s261(7) of the Health and Social Care Act 2012 as the relevant legal basis within section 3 and as advised by the IG Advisor to IGARD. 8. To clarify that references to University of Oxford in section 5 should be updated to refer to Nuffield Department of Population Health, as may be appropriate.
2.4	<u>Rand Europe: outcome evaluation of Offender Liaison and Diversion Trial Schemes (Presenter: Louise Dunn) NIC-66034-M7B8W</u> **Application:** This was a new application for a bespoke linkage of Hospital Episode Statistics (HES) Accident & Emergency (A&E), Mental Health Minimum Data Sets (MHMDS) and Improving Access to Psychological Therapies (IAPT) data set to a cohort of service users. This application was previously considered by IGARD on the 11 January 2017 when IGARD were unable to recommend for approval: consent did not provide an adequate legal basis. **Discussion:** IGARD were unclear if the applicant was using consent to recruit to the study and NHS Digital confirmed that they had used consent. However, it was not clear if recruitment to the study was continuing or if it had closed and IGARD suggested that it be explicitly stated in section 5 of the application if the recruitment had closed and noted that if recruitment to the study had closed, that the legal basis to receive and process data should be clearly outlined within the application. IGARD noted that the application may have been written prior to General Data Protection Regulation (GDPR) and suggested that the wording be updated to be clear what had happened prior to the implementation of GDPR on the 25th May 2018 and what steps had been undertaken to comply with GDPR since that date. IGARD noted that supporting document 1 (flow of data) provided with the application provided better explanations of the datasets and suggested this wording be used within section 5 for clarity and plain English. It was noted that supporting document 9 (fair processing information) provided was a live document but that the applicant may wish to review this document to correct a number of typos identified and be written in a language suitable for a lay reader. **Outcome:** recommendation to defer, pending: 1. To confirm if recruitment to the study has closed and update within the abstract and section 5. 2. If recruitment to the study has closed, to clarify the legal basis to receive and process data.

	3. To update the wording throughout the application to be clear what has previously occurred prior to 25th May and steps undertaken to comply with GDPR since. 4. To update the explanation of the datasets within section 5 with the clear wording provided in the data flow diagram. The following advice was given: 1. IGARD suggested that the applicant update the supporting document 9 to correct typos and in language suitable for a lay reader.
2.5	<u>NHS England: National Cancer Waiting Times Monitoring Data Set (NCWTMDS) (Presenter: Rachel Farrand)</u> NIC-192305-X3T0Y **Application:** This was an amendment application for the purpose of accessing the National Cancer Waiting Times Dataset (NCWTMDS) via a new NHS Digital system: iView tool. NCWTMDS is a national patient level data collection by NHS Digital under a Direction from NHS England and the data is used for monitoring times taken to diagnose and treat patients with cancer and ensures these are in line with the expectations and rights of patients in the NHS Constitution. NHS Digital noted that section 5b would be updated to clarify the three different teams involved in the analysis of the data. **Discussion:** IGARD agreed with NHS Digital that section 5b be updated to clarify the three teams involved in the analysis of the data. IGARD asked how the new iView Tool system differed to the previous access via Exeter and NHS Digital noted iView was a modern intuitive system with a more secure platform and appropriate controls. IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested. IGARD queried if the Direction had been formally approved and NHS Digital confirm that it had, however IGARD suggested that confirmation be provided. IGARD noted that the application stated that ethics approval was not required, however since ethics approval is required for this application that the application be updated with appropriate standard ethics approval wording. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. To provide confirmation that the Direction has been formally approved. The following amendments were requested: 1. To include the standard ethics approval wording within the application. 2. To update section 5b of the application to clarify the three different teams involved in analysing the data. It was agreed the conditions would be approved OOC by the IGARD Members

2.6	University of Leeds: Melanoma Lifestyle Study (Presenter: Louise Dunn) NIC-89962-D7V5Q **Application:** this was a new application requesting access to Cancer and Mortality Data for the Melanoma Lifestyle study. The Study recruited from November 20017 with the cohort recruitment completed in September 2014 and was a case-control study where cases were melanoma patients who had relapsed from melanoma. NHS Digital noted that the IG Advisor to IGARD had confirmed that the legal basis to disseminate the data should be s261(2)(c). **Discussion:** IGARD noted that the advice to amend the legal basis to s261(2)(c) within section 3 of the application as the legal basis to disseminate data. IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested. IGARD queried supporting document 7 (newsletter for participants Nov 2017) and noted that the newsletter provided contained a different study title, however NHS Digital confirmed that the wrong newsletter had been provided and the one provided was not relevant. IGARD asked that the latest newsletter provided to the study participants be provided. IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5b of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement. IGARD noted that supporting document 2 (Research Ethics Committee (REC) application form) was dated 24 July 2007 and for 10 years in duration, therefore ended in 2017 and that supporting document 4 (progress report dated 18 April 2016) noted a progress report had been submitted to REC but suggested that evidence be provided that ethics had been extended beyond 10 years by providing a copy of the REC extension letter. IGARD also noted that protocol version 1.1 had been provided to the REC but that version 2 had been provided to IGARD as a supporting document and asked that confirmation be sought that the ethics review had been based on the updated version 2 protocol or whether the changes made were considered minor amendments and therefore not considered by REC. IGARD queried the storage of the clinical data and if the NHS Digital security advisor was content. NHS Digital noted that data would only be stored at those locations outlined in the application, however IGARD suggested that the NHS Digital Security Advisor confirm they are content that data will not be held at any other location other than those outlined in the application. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. Providing a copy of the applicant's REC extension letter. 3. Confirmation within section 5b of the application that the applicant will not link the data further and the only data linkages are those permitted under this application. 4. To provide a copy of the latest newsletters provided to study participants, as outlined in section 5 of the application. The following amendments were requested:

	1. Confirmation of whether the applicant has sought updated ethics review based on the updated protocol, or whether the changes made were only considered minor amendments. 2. To include the legal basis s261(2)(c) of the Health and Social Care Act 2012 as the relevant legal basis within section 3 and as advised by the IG Advisor to IGARD. 3. To confirm within section 5 that NHS Digital security advisor has confirmed they are content that data will not be held in any other location than those outlined in the storage section of the application. It was agreed that the conditions would be approved OOC by the IGARD Members
2.7	University of Cambridge: understanding the long term effects of whole blood and platelet donation (Presenter: Kimberley Watson) NIC-309034-C7M7W **Application:** This was an amendment application covering Hospital Episode Statistics (HES) linked to cohort and a request for linked Office for National Statistics (ONS) data. The aim of the current pilot study is to determine whether it is operationally feasible to establish a non-identifiable electronic hemovigilance platform which will allow NHS Blood and Transplant (NHSBT) to address immediate questions relation to donor health. As part of this pilot study retrospective linkage is being sought between ONS records and previously linked HES-NHSBT blood donor records. NHS Digital noted that the applicant's fair processing reference anonymised data. NHS Digital noted that section 3 had been updated to include the legal basis to disseminate date for both Data Controllers. **Discussion:** IGARD noted that the legal basis for both Data Controllers should be updated within section 3 of the application. IGARD queried if any additional data linkages would be undertaken and that it be explicit within section 5b of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement. IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however IGARD suggested that a clear justification for each choice indicated should be given in terms of how the specific criteria and additional requirements would be met since the applicant would need to satisfy the relevant tests associated with the legal basis suggested. IGARD noted the supporting document 9 (continued annual approval) provided was over a year old and asked that evidence be provided that s.251 was still in place for the project outlined within the application. IGARD noted that the MRP listed in the application had expired on 15 January 2018 and that evidence be provided that ONS legal basis was in place including evidence of Approved Researcher Status for the named individual. IGARD noted that University of Cambridge should publish a fair processing compliant with GDPR and suggested that NHS Digital work with the Data Controller along with removing reference to anonymised data and replacing with pseudonymised data. IGARD also noted that supporting documents 10 and 11 (patient leaflets) provided should provide more granular information and that NHSD Digital work the applicant. It was also suggested that the applicant update their study newsletter to provide up to date information with regard to the research being undertaken. **Outcome:** recommendation deferred, pending:

	1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met for both Data Processors. 2. Confirmation within section 5b of the application that the applicant will not link the data further and the only data linkages are those permitted under this application. 3. Providing evidence that s.251 support is still in place for the project. 4. To provide evidence that ONS legal basis is in place. 5. Reference within the applicant's fair processing notice to anonymised data should be updated to pseudonymised data The following advice was given: 1. IGARD suggested that the study newsletter be updated to provide up to date information with regard to the research being undertaken.
3	**AOB** None

Appendix A: Summary of Open Actions

Date raised	Action	Owner	Updates	Status
20/04/17	IGARD Chair to contact key stakeholder organisations regarding the benefits of uses of data to feed into the IGARD annual report.	IGARD Chair	14/09/17: Ongoing. It was agreed this would be discussed during the educational session. 07/12/17: Ongoing. It was agreed to bring the first draft to January's education session. 08/02/18: it was agreed the updated draft be brought to the March education session 01/03/18: the March education session was cancelled, and it was agreed to take the draft annual report to the April education session. 05/04/18: to seek clarification from the Chair if stakeholders have been approached and to bring back the draft to the May education session. 12/04/18: The Chair noted he was yet to contact external to NHS Digital stakeholders. 19/04/18: IGARD chair to update members at May's education session. 03/05/18: The Chair of IGARD noted that he would be contacting key stakeholders over the coming weeks. 07/06/18: 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	10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks. 24/08/17: IGARD received a verbal update on the work that had taken place following both audits and verbal assurances that NHS Digital were content with the level of risk involved in this organisation	Open

			continuing to act as a data processor. IGARD welcomed this update and requested written confirmation. 31/08/17: IGARD were notified that the requested written confirmation should be provided within one day. 14/09/17: An email response had been circulated on 31 August, and IGARD noted that they were awaiting receipt of the post-audit report. 05/04/18: IGARD Secretariat had contacted Garry Colman and were awaiting a response. 07/06/18: ongoing	
31/08/17	Garry Coleman to report back on how cancer registration data was previously described as pseudonymised PDS data within older versions of applications, and present to a future education session on changes to how Medical Research Information Service (MRIS) reports are now shown within applications.	Garry Coleman	22/02/18: IGARD Secretariat to contact Garry Coleman to suggest presentation at the June education session. 05/04/18/18: IGARD Secretariat were awaiting a response. 07/06/18: ongoing	Open
15/03/18	Stuart Richardson to provide a briefing note clarifying the contractual arrangements in place, the structure, enforcement strategy and how the agreements worked together so that the data disseminated by NHS Digital would be protected and provide a verbal update to IGARD on the progress of this note by 5 April 2018.	Gaynor Dalton	05/04/18: A verbal update was provided that individual Data Sharing Framework Contracts (DSFC) were issued yet Data Sharing Agreements were joint Data Controllership and that DSFC's placed exactly the same terms and conditions upon organisations and NHS Digital believe the position to be acceptable. IGARD noted the verbal update and asked that a briefing note be provided by NHS Digital confirming the arrangements in place by the end of April 2018. 26/04/18: IGARD secretariat were awaiting a response following issue of a reminder	Open

			03/05/18: It was noted the issue was wider than DSfC applications and applies to all DARS applications, the action owner was amended to the Head of Data Access, Gaynor Dalton. 10/05/18: The Director Data Dissemination noted that a briefing note would be provided to IGARD for the 24 May meeting. 24/05/18: it was noted that a briefing note had not been provided to IGARD. 07/06/18: ongoing	
12/04/18	IGARD Members to consider the HRA guidance on GDPR published on line IGARD Chair to provide feedback to the Caldicott Guardian	IGARD IGARD Chair	19/04/18: IGARD members had considered the HRA guidance and asked the IGARD Chair to provide feedback to the Caldicott Guardian. 26/04/18: IGARD Secretariat awaiting comment following issue of a reminder. 03/05/18: the Chair of IGARD to provide a copy of the email sent to the Caldicott Guardian to the Secretariat team 07/06/18: ongoing	Open
26/04/18	Stuart Richardson to complete, for transparency, on all future CCG applications the data already held information at section 3a, including such data as may be held under a different Data Sharing Agreement / NIC number.	Stuart Richardson	07/06/18: ongoing	Open
26/04/18	Stuart Richardson to provide for all future CCG applications a data flow diagram detailing all previously approved data flows alongside a new data	Stuart Richardson	07/06/18: ongoing	Open

	flow diagram outlining the data flows for the presented application.			