Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 2 August 2018

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

In attendance: Louise Dunn, Anna Duggan (item 2.2 and 2.3), James Humphries-Hart, Karen Myers, Katharine Robbins, Kimberley Watson, Vicki Williams.

Apologies: Sarah Baalham, Anomika Bedi, Nicola Fear.

1	**Declaration of interests** There were no declarations of interest. **Review of previous minutes and actions** The minutes of the 26 July 2018 IGARD meeting were reviewed by IGARD and agreed as an accurate record of the meeting. The outstanding actions were reviewed. **Out of committee recommendations** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	<u>Group 195 CCG's – CSDS: Amendment for 195 CCG's to receive Community Services Data Set (CSDS) (Presenter Katharine Robbins / James Humphries Hart)</u> **Briefing Paper and Application:** This was an amendment application for 195 Clinical Commissioning Group's (CCG's) to receive pseudonymised Community Services Data Set (CSDS) which expands the scope of the existing Children and Young People Health Service (CYPHS), by removing the 0-19 age restriction and will therefore include a wider remit of patients. The data is analysed so that health care provision can be planned to support the needs of the population within the CCG area. The application had been withdrawn by the presenter at the 5 July 2018 meeting. **Discussion (Briefing Paper):** IGARD noted the contents of the revised briefing note which had been previously presented to IGARD on the 5 July 2018. IGARD and NHS Digital discussed the points raised at the July meeting including: how NHS Digital would be supporting the care providers collecting data in terms of meeting their legal requirements; explaining who the "providers of publicly funded community services" are; explaining where the mandate has come from for such providers to collect data (particularly noting that the dataset would now cover elderly and a great many more vulnerable service users); explaining how the actions set out on the final page of the note will be undertaken (e.g what are "reasonable efforts" to remove identifying free text?) and providing justification for the statement that the data is "anonymised". IGARD suggested further amending the briefing note to fully address those points and bringing back to a future IGARD meeting to support the associated application. **The following comments were made:** 1. To reinstate references to the GDPR and update sections 4 and 6 of the briefing paper to refer explicitly to the lawful basis for processing under the GDPR

	2. To provide a detailed analysis, particularly in the context of the large number of datasets involved and extensive linkage, as to why the data is regarded as anonymised in line with the ICO code (IGARD noted that such an analysis is separate from an assessment of the security measures that may be in place). 3. The CSDS fair processing notice to be amended to meet NHS Digital's fair processing criteria and is GDPR compliant specifically: explicitly referencing how the data is collected, better describing the CSDS data set, referencing the actors involved, the purpose of, and the type of, processing being undertaken. **Discussion (Application):** 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 and as per recent discussions between NHS Digital and IGARD, including the processing being undertaken and section 11(1) DPA 2018. IGARD also queried the CSDS dataset including the organisations involved, the processing activities and the purpose of the processing since it was not clear in the narrative how the dataset was moving from 0-19 years to include all age groups and suggested that section 5 be updated to clearly describe that by widening the age range for the dataset the number of providers collecting and supplying the data would increase greatly. IGARD noted the applicant should provide a fair processing notice that it is compliant with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice, including how the Data Controllers meet their notice requirements under GDPR. **Application Outcome:** the application was deferred, pending: 1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including (but not limited to) the processing being undertaken, and section 11(1) DPA 2018. 2. To describe in section 5 in more detail the background to, and reasons for, the creation of the new CSDS data set, the purpose of the processing, the processing activities and the organisations involved. 3. To include in the application the fair processing section explaining how the data controllers meet their notice requirements under the GDPR.
2.2	<u>University of Warwick: MR1454 - PARAMEDIC2 (Prehospital Assessment of the Role of Adrenaline: Measuring the Effectiveness of Drug administration In Cardiac arrest) (Informed consent cohort) (Presenter: Louise Dunn) NIC-150856-G6P5R</u> **Application:** This was a new application for identifiable Civil Registrations data, Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data. The PARAMEDIC 2 trial is aiming to evaluate how safe and effective adrenaline is as a treatment for patients who suffer out of hospital cardiac arrest. There is a consistent pattern across research studies, which suggests adrenaline improves initial survival but may lower overall survival and increases brain damage. This application relates to the cohort who have given their informed patient consent. **Discussion:** IGARD welcomed the application and noted that it is an important and topical study and are aware that University of Warwick have been doing a lot of important work looking at the use of adrenaline for patients who suffer a cardiac arrest and have recently published another part of the study.

	IGARD suggested that the abstract be amended to reference patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations to those that have consented". NHS Digital noted that the University of Warwick were sharing identifiable data with NICOR / ICNARC in order for the work to be undertaken, however IGARD asked for further clarification on the data flow diagram in supporting document 4 and in section 5b whether data would be flowing from NHS Digital to ICNARC / NICOR and vice versa and suggested this be made clear within the supporting document and 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 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. IGARD noted that the legal basis at the top of supporting document 4 (data flow diagram) should be updated to refer to the correct section of the Statistics and Registration Service Act 2007 (SRSA). IGARD queried whether recruitment had closed on the study and NHS Digital noted that recruitment had finished; it was suggested that this was clarified within section 5. IGARD asked for clarification as to the purpose of supporting document 20 and suggested that if it is not required for the purpose of this application that it be removed from the application pack on CRM. IGARD expressed concern over some inadequacies in the consent information provided and suggested that the applicant contact patients in the form of a newsletter which should include the updated fair processing notice. **Outcome:** recommendation to approve from such time as ONS data has moved to NHS Digital controllership and subject to the following conditions: 1. Confirmation there is no flow of data from NHS Digital to ICNARC / NICOR and confirmation there is no flow of data from ICNARC / NICOR to NHS Digital. 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. Confirmation within section 5 of the application that the individual 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 the appropriate action in the event of a breach. The following amendments were requested: 1. To update the abstract to amend references to patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented". 2. To update reference to SRSA 42(4) in supporting document 4, data flow diagram. 3. To confirm in section 5 that there will be no future recruitment to the study. 4. To update the abstract to state that for GDPR that they are not relying on consent. The following advice was given:

	1. IGARD suggested that the applicant may wish to consider whether the updated fair processing notice information be included in the next iteration of the newsletter which could be sent to survivors after an appropriate list clean. It was agreed that the condition would be agreed OOC by the IGARD members.
2.3	<u>University of Warwick: MR1455 - PARAMEDIC2 (Prehospital Assessment of the Role of Adrenaline: Measuring the Effectiveness of Drug administration In Cardiac arrest) (s251 cohort) (Presenter: Louise Dunn) NIC-56872-T9B0J</u> **Application:** This was a new application for Civil Registrations data, Hospital Episode Statistics (HES) and Medical Research Information Service (MRIS) data. The PARAMEDIC 2 trial is aiming to evaluate how safe and effective adrenaline is as a treatment for patients who suffer out of hospital cardiac arrest. There is a consistent pattern across research studies, which suggests adrenaline improves initial survival but may lower overall survival and increases brain damage. This application relates to the cohort with a s251 support in place. **Discussion:** IGARD welcomed the application and noted that it is an important and topical study and are aware that University of Warwick have been doing a lot of important work looking at the use of adrenaline for patients who suffer a cardiac arrest and have recently published another part of the study. NHS Digital noted that the University of Warwick were sharing identifiable data with NICOR / ICNARC in order for the work to be undertaken, however IGARD asked for further clarification on the data flow diagram in supporting document 4 and in section 5b whether data would be flowing from NHS Digital to ICNARC / NICOR and vice versa and suggested this be made clear within the supporting document and 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 queried if 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. IGARD noted that the legal basis at the top of supporting document 4 (data flow diagram) should be updated to reflect the correct part of the Statistics and Registration Service Act 2007 (SRSA). IGARD queried whether recruitment had closed on the study and NHS Digital noted that recruited had finished, it was suggested that this was clarified within section 5. **Outcome**: recommendation to approve from such time as ONS data has moved to NHS Digital controllership and subject to the following conditions: 1. Confirmation there is no flow of data from NHS Digital to ICNARC / NICOR and confirmation there is no flow of data from ICNARC / NICOR to NHS Digital. 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. Confirmation within section 5 of the application that the individual 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 the appropriate action in the event of a breach. 4. To update section 3b to confirm that the legal basis for dissemination of Civil Registration Data is the Health and Social Care Act 2012. The following amendments were requested:

	1. To update reference to SRSA 42(4) in supporting document 4, data flow diagram. 2. To confirm in section 5 that there will be no future recruitment to the study. It was agreed that that condition would be agreed OOC by the IGARD members.
2.4	<u>University Hospitals Bristol NHS Foundation Trust: HES/ONS data for the AIRWAYS-2 cluster randomised trial. (Presenter: Louise Dunn) NIC-35562-V6G5W</u> **Application:** This was a new application from South Western Ambulance Service NHS Foundation Trust as the Data Controller requesting a one off linked HES-ONS extract linked to their recruited cohort of approximately 4,000 with request to receive data for each patient for the 6-month period after their cardiac arrest. The data provided will be linked to trial data collected by the Clinical Trails and Evaluation Unit at University Hospitals Bristol NHS Foundation Trust. This was previously deferred at IGARD on the 7th June 2018 pending; providing the relevant sections under Article 6 and 9 of GDPR; a clear explanation within section 5 of the application of the roles and responsibilities of the collaborators outlined and the legal basis for them to receive and process data; clarify why the organisations listed in supporting document 1 are not listed as joint Data Controllers; confirm within section 5b that the applicant will not link the data further; confirmation within section 5 that the individuals accessing the data are substantive employees with the appropriate honorary contract in place; to confirm within section 5 that those patients who are deceased upon arrival at hospital are included within the study; to include the legal basis s261(7) of the Health and Social Care Act 2012 as the relevant legal basis within section 3; to clarify that references to University of Oxford in section 5 should be updated to refer to Nuffield Department of Population Health. NHS Digital to amend reference to the University Hospitals Bristol NHS Foundation Trust being Data Processor in both the abstract and application. **Discussion:** 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 and as per recent discussions between NHS Digital and IGARD, including reference to the public interest condition. IGARD noted that schedule 1 part 1 had been referenced within the abstract, however suggested that NHS Digital work with the IG Advisor to IGARD to correctly list the DPA 2018 schedule 1 Part 1 references against each of the Article 9 legal basis cited and clearly describe how the schedule conditions are met. The AIRWAYS-2 trial involved incapacitated patients and IGARD observed that certain requirements of the Mental Capacity Act 2005 would be met by the trial's Research Ethics Committee approval. IGARD noted that the description of the consented cohort and s 251 cohort do not appear to be clear and advised that the following wording within the abstract: "Originally the participants who survived cardiac arrest…." be amended to "Section 251 support was originally given to identify and retain survivors' NHS numbers. Patients who survived and regained capacity were approached for consent to follow up. The latest CAG amendment now provides support for receipt of identifiers by NHSD and linkage to HES of the whole enrolled cohort - not just those that survived initial intervention for their cardiac arrest."

	IGARD noted that the abstract should be amended to make clear that the applicant is a Foundation Trust and not a University. IGARD noted that new DSA standard clause wording should be agreed with regard to the processing of data by individuals on honorary contracts and it was agreed that this would be discussed at a future IGARD meeting. **Outcome:** recommendation to approve subject to the following conditions 1. To agree the wording of a new DSA standard clause with regard to the processing of data by individuals on honorary contracts. 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 in relation to the University of Oxford. The following amendments were requested: 1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018 and public task for Foundation Trusts. 2. To update the abstract to clearly describe the cohort and s251 support. 3. To update section 5b wording from "Those patients who are deceased upon arrival at hospital are included within the study" to "Patient identifiable data (Study ID, NHS Number, Date of Birth, Surname, Forename, Gender, Postcode) of all patients enrolled in the study, whether they survived intervention or not, be sent by UH Bristol to NHS Digital." 4. To update the abstract to be clear that the applicant is a Foundation Trust not a University. 5. To remove reference to the University of Bristol as a Data Processor from within the abstract. It was agreed that the condition would be agreed OOC by the IGARD members.
2.5	<u>Clinical Practice Research Datalink (CPRD): BisCK Study (Risks and Benefits of bisphosphonate use in patients with chronic kidney disease) (Presenter: Kimberley Watson) NIC-113017-L9R3N</u> **Application:** This was a new application requesting trusted third-party data linkage facility for the UK Renal Registry data (part of the Renal Association) and CPRD data. The bridge file of Hospital Episode Statistics (HES) to Diagnostic Imaging Datasets (DIDs) data will be used to assess the association between the use of oral bisphosphonates (anti-osteoporosis medication) and the progression (stage worsening or entering renal replacement therapy / transplant) of kidney disease in NHS patients with moderate or severe chronic kidney disease). This was previously deferred at IGARD on the 14th June 2018 pending; providing the relevant sections under Article 6 and 9 of GDPR; to clarify the legal basis to disseminate data for CPRD; provide evidence that a s. 251 is in place; CPRD to update their Fair Processing Notice; University of Oxford to provide a Fair Processing Notice to meet NHS Digital's fair processing criteria; the Fair Processing section to be amended to include the new standard wording; and to clarify within section 5 that Aimes Grid Services Ltd would not have access to data.

Discussion: IGARD noted that the relevant sections within Article 6 and 9 of GDPR should be included within the application clarifying the justification for the choice of each section and how this meets the criteria and requirements are met.

IGARD queried the legal basis for data to be disseminated to CPRD, on the basis that further information was required to support the assertion that it was a public authority and noted that HRA CAG letters were provided for 2017 but suggested that evidence be provided that s.251 support was currently in place.

IGARD noted that historic phrasing was being used in section 4 Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". IGARD noted their endorsement of NHS Digital's review of HQIP's privacy notice and suggested they update in line with GDPR requirements. IGARD noted that the legal basis within section 3b should be amended to reflect section 261(7) of the Health and Social Care Act 2012.

IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that it be updated to include an accurate description of the processing activities undertaken, and the level and type of data being processed. IGARD queried how CPRD and general practices were meeting their Data Controller obligations under GDPR to provide privacy notices.

IGARD also noted that the University of Oxford's fair processing notice did not meet NHS Digital's processing criteria for privacy notices and suggested that it be updated by the University of Oxford to contain the relevant information on the University of Oxford website rather than incorporating by reference to links to other fair processing notices references on other organisations websites (such as NHS Digital and the Renal Association).

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. To clarify the legal basis to disseminate data for CPRD.
3. Providing evidence that s.251 support is in place and for the cohort described within the application.
4. CPRD to update their Fair Processing Notice to meet the NHS Digital's fair processing criteria for privacy notices including accurate description of the processing activities, and level and type of data processed.
5. University of Oxford to provide a Fair Processing Notice to meet NHS Digital's fair processing criteria for privacy notices including removing links to other fair processing notices referenced on their website.
6. The Fair Processing section to be amended to include the new standard wording: "All data required by the Data Controller under this application is pseudonymised and therefore 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."
7. To update the legal basis within section 3b to section s.261(7).

2.6	University College London: MR104 – British Regional Heart Study (Presenter: Kimberley Watson) NIC-148411-Q64H8 **Application:** This was a renewal application for Medical Research Information Service (MRIS) data. The data is being requested for the British Regional Heart Study, a cohort study of cardiovascular disease and other common chronic diseases. The cohort comprises of men aged 75-94 who joined the study in 1978 and the data will be used to support the investigation into the cause, mechanisms and prevention of these age-related conditions in older men and allow the researchers to test new hypotheses in cardiovascular ageing. **Discussion:** IGARD queried if s 251 support supports the use of Office of National Statistics data and asked for this be clarified within the application, noting that a copy of the HRA CAG register had been provided however this referred to a 'class action' rather than specifically to the use of ONS data. IGARD queried how the Regional Heart Study relates to the wider study outlined in the application and asked for this to be explicitly stated within section 5 of the application how the two relate and how the regional study enhances the wider study. IGARD noted that schedule 1 part 1 had been referenced within the abstract, however suggested that NHS Digital work with the IG Advisor to IGARD to correctly list the DPA 2018 schedule 1 Part 1 references against each of the Article 9 legal basis cited and clearly describe how the schedule conditions are met. IGARD expressed a view that the privacy notice did not in fact meet NHS Digital's fair processing criteria and suggested the following wording be inserted in Section 4: "All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". IGARD noted that the privacy notice notes that consent has been sought and advised that this should be amended to instead reflect the s251 support. IGARD queried section 5a in relation to the data that has been received to date by the applicant and the additional data the applicant is now requesting and suggested that, for transparency, clarification be provided. **Outcome:** recommendation to approve subject to the following conditions: 1. Clarification that s.251 support supports the use of ONS 2. To explicitly state within section 5a how this wider programme of research relates to the British Regional Heart Study. The following amendments were requested: 1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018, removing the duplicate text with regard to the Royal Charter and removing the text in paragraph 3 which starts "4. The College, subject to this Our Charter …" 2. To amend section 4 with the standard wording "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month".

	3. To update the abstract to confirm that the privacy notice does not meet NHS Digital's fair processing criteria for privacy notice including removing reference to consent being sought. 4. To clarify within section 5a what data they already hold and what data they are requesting. It was agreed that the condition would be agreed OOC by the IGARD members.
2.7	<u>University College London (UCL) - Evaluating variation in special educational needs provision for children with Down syndrome and associations with emergency use of hospital care. (Presenter: Kimberley Watson) NIC-50975-X6N3J</u> **Application:** This was a new application for month and year of death to be provided use PDS which will be linked to a cohort of 119,000 derived from the Public Health England (PHE) National Down Syndrome Cytogenetic Register (NDSCR) and the PHE already-held Hospital Episode Statistic (HES) data. The study will look at variation across England in health, social care and education services for children with Down Syndrome and determine the impact on emergency use of hospital care. This was previously deferred at IGARD on the 3rd May 2018 pending; clarification of the legal basis under GDPR for the linkage of HES data provided to PHE under the MoU to the registration data held by PHE; clarification of the legal basis under GDPR for the flow of identifiable data from PHE to NHS Digital; clarification of the control cohort and the legal basis for PHE to sample childhood data from the general population to generate the control group under GDPR; to clearly define the role and involvement of ADRN and the other collaborators within the network as well as the Institute of Education; to clarify within the application that the 'Leeds team' refers to NHS Digital staff based in Leeds, to ensure consistency of the terms 'Down Syndrome' and 'Down's Syndrome' throughout section 5 of the application; to provide a fair processing notice that meets NHS Digital's fair processing criteria including published and accessible and to add PHE to the information governance toolkit special condition. **Discussion:** IGARD welcomed the application and noted its significance and complexity. IGARD queried the legal basis under GDPR for the linkage of HES data provided to PHE under the Memorandum of Understanding (MoU) to the registration data held by PHE. NHS Digital confirmed that this linkage was acceptable use under the MoU, however the legal basis for PHE to do the linkage was not clear since the MoU was not a legal gateway. IGARD noted that under GDPR there were different kinds of processing and queried which of the flows of identifiable data from PHE to NHS Digital were covered and that it be clearly stated what legal basis under GDPR was being used for the flow of the identifiable data from PHE to NHS Digital. IGARD asked for clarification of the legal basis for Public Health England to sample childhood data from the general population to generate the control cohort and also asked for amendment in section 5b clarifying how the control group is selected and noting that there are 9 controls per 1 case. IGARD noted that schedule 1 part 1 had been referenced within the abstract, however suggested that NHS Digital work with the IG Advisor to IGARD to correctly list the DPA 2018 schedule 1 Part 1 references against each of the Article 9 legal basis cited and clearly describe how the schedule conditions are met. IGARD noted that historic phrasing was being used in section 4 Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a

	privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and supported NHS Digital's review. **Outcome:** recommendation to defer, pending: 1. Clarification of the legal basis under GDPR for the linkage of HES data provided to PHE under the MoU to the registration data held by PHE. 2. Clarification of the legal basis under GDPR for the flow of identifiable data from PHE to NHS Digital. 3. Clarification of the control cohort and the legal basis for PHE to sample childhood data from the general population to generate the control group under GDPR, including within section 5b that there are 9 controls per 1 case. 4. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018, removing the duplicate text with regard to the Royal Charter and removing the text in paragraph 3 which starts "4. The College, subject to this Our Charter …" 5. To amend section 4 with the standard wording "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is complaint with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". The following advice was given: 1. IGARD endorsed NHS Digital's review that the applicant's privacy notice does not meet NHS Digital's fair processing criteria for privacy notices.
2.8	<u>University of Liverpool A study looking at Emergency Department attendances at NHS hospitals by people with epilepsy in the SAFE Trial (Presenter: Kimberley Watson) NIC-150521-F2Q1V</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistic (HES) data. The University of Liverpool has developed seizure first aid training for part of the epilepsy population and has recently completed a pilot randomised trial of it, called the Seizure First Aid Training for Epilepsy, SAFE trial. This study is looking to see how helpful the Seizure First Aid Training course is and to help identify whether it supports people with epilepsy and their family and friends get the information they need and whether it makes them more confident managing seizures. The results from this pilot will inform how best to complete a full trial so that it can be well positioned to generate the scientifically rigorous evidence required to inform care and maximize patient outcomes. **Discussion:** IGARD noted that the consent material provided was for data containing information of the overall number of HES A&E visits, however the extract would contain confidential clinical information not part of the additional consent provided and suggested that further justification be provided for their request of the whole HES dataset. NHS Digital noted that the applicant would not receive NHS Number, however IGARD asked for clarification that the applicant will not receive NHS number for the cohort and this be included in section 5 of the application

	IGARD suggested that the abstract be amended to reference patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations to those that have consented". IGARD noted that schedule 1 part 1 had been referenced within the abstract, however suggested that NHS Digital work with the IG Advisor to IGARD to correctly list the DPA 2018 schedule 1 Part 1 references against each of the Article 9 legal basis cited and clearly describe how the schedule conditions are met. IGARD asked for section 5b be amended to reflect that the data would be stored and destroyed in accordance with GDPR, not the Data Protection Act 2018. IGARD queried whether funding was still in place since the documentation provided stated that funding had been awarded in 2014 and asked for this to be clarified within section 8 along with a copy of the funding letter. IGARD raised a query about the type of data received by NHS Digital and suggested this be clearly stated within section 5b. IGARD noted that within section 5 an amendment should be made to remove reference to "pseudo-anonymised" and "anonymised" and should be amended to say "pseudonymised". **Outcome:** unable to recommend for approval. 1. The consent provided was for the overall number of HES A&E visits only, however the HES A&E extract would contain confidential clinical information which was not part of the additional consent provided. 2. Confirmation that the applicant will not receive NHS numbers for the cohort. 3. To update the abstract to amend references to patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented". 4. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD, including (but not limited to) reference to the public interest condition under the DPA 2018. 5. To update section 5b wording from "…stored and destroyed in accordance with the Data Protection Act 2018." To "…stored and destroyed in accordance with GDPR." 6. To update section 8 to confirm that funding awarded in 2014 is still in place. 7. To update section 5b to clearly describe the data received by NHS Digital. 8. Section 5 to be updated to remove reference to "pseudo-anonymised" and "anonymised" to change to "pseudonymised".
3	**AOB** IGARD noted that NHS Digital may wish to consider referring to the statutory requirements of the Mental Capacity Act (specifically in reference to Research Ethics Approval) in the relevant NHS Digital standards being developed. IGARD noted that this was Chris Carrigan's final meeting and wished to extend their thanks to his chairmanship over the last 18 months and the work undertaken during his tenure on IGARD.