

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 30 August 2018

Members: Sarah Baalham, Jon Fistein, Kirsty Irvine (Chair), Eve Sariyannidou.

In attendance: Ibrahim Ali (observer), Dave Cronin, Louise Dunn, Rachel Farrand, James Humphries-Hart, Karen Myers, Katharine Robbins (item 2.13), Sharon Thandie (item 2.13), Kimberley Watson, Vicki Williams.

Apologies: Joanne Bailey, Anomika Bedi, Nicola Fear.

1	<p>Declaration of interests:</p> <p>Jon Fistein noted his professional links to the parties in University of Sheffield [NIC-194387-K3H5K] and would not be part of the discussion. It was agreed that Jon would not remain in the meeting for the discussion of that application.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 23 August 2018 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p>
2	Data applications
2.1	<p><u>University of Liverpool A study looking at Emergency Department attendances at NHS hospitals by people with epilepsy in the SAFE Trial (Presenter: Dave Cronin) NIC-150521-F2Q1V</u></p> <p>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.</p> <p>The application was been previously considered on the 2nd August 2018 when IGARD had been unable to recommended for approval pending; 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; confirmation required that the applicant will not receive NHS numbers for the cohort; to update the abstract to amend references to patient consent and the common law duty of confidentiality; to update the abstract sections on Article 6 and 9 of GDPR; to update section 5(b) wording to "...stored and destroyed in accordance with GDPR."; to update section 8 to confirm that funding awarded in 2014 is still in place; to update section 5(b) to clearly describe the data received by NHS Digital and to update section 5 to remove reference to "pseudo-anonymised" and "anonymised" to change to "pseudonymised".</p>

	<p>Discussion: IGARD noted that the application had been updated to reflect the points made on 2 August, however they observed that section 5(b) still referred to diagnostic codes and suggested that this be removed.</p> <p>IGARD noted that the fields sought by the application were not expressly noted in the table in section 3(b) and asked for these to be explicitly stated.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To remove reference to "...any associated ICD diagnostic code..." from section 5(b). 2. To explicitly state the date and NHS number fields being provided in section 3(b).
2.2	<p><u>The Nuffield Trust: Rapid Service Evaluation Team (RSET) (Presenter: Dave Cronin) NIC-194629-S4F9X</u></p> <p>Application: This was a new application for both identifying and pseudonymised Hospital Episode Statistic (HES) data to conduct rapid evaluations of health and care service innovations, in close partnership with those who deliver, manage and use these services. The RSET Team will enable provision of formative, as well as summative feedback to those implementing innovations in health and care services.</p> <p>Discussion: IGARD welcomed the application and noted the importance of the work and acknowledged the Nuffield Trust's ability to respond rapidly to service evaluation requests. References within the application to decisions being made by a committee comprising a number of different parties and to a "partnership approach" prompted IGARD members to query the involvement of such parties and their exact role.</p> <p>IGARD queried what the criteria and scope was of the three projects outlined in the application and asked for this to be clarified along with the framework criteria for future projects and to state how they will fall within the same scope.</p> <p>IGARD queried the "rapid response" aspect of the project and asked for further information clarifying the importance and value of this to determine if it is possible to set out criteria now for future applications to be assessed against.</p> <p>It was suggested that within one month of dissemination of the data, NHS Digital should check whether the applicant had published a privacy notice that is compliant with the GDPR notice requirements. IGARD observed that section 4 of the application should be updated to refer to the privacy notice being provided within "one month" of receipt of data. IGARD noted the special condition that states 'The Nuffield Trust shall ensure access to data disseminated with NHS Digital is strictly prohibited and must not be accessed by Wavex Technology' was not clear and suggested that is be amended.</p> <p>Outcome: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> 1. To provide an explicit statement within section 5(b) that Nuffield will carry out the work alone and giving a clear explanation, within section 5 of the application, the roles and responsibilities of the other organisations outlined within the application, including their role in the design and performance of the project and any data they may have access to and being clear the Data Controller is solely responsible for directing the project. 2. To clarify the criteria for assessment and the scope of the three project outlines provided and to set out framework criteria for future projects and how they will fall within the same scope. 3. To provide further information about the importance and value of the "rapid response" aspect of the project

	<ol style="list-style-type: none"> 4. Within one month after the dissemination of the data, NHS Digital should check whether the applicant has published a privacy notice that is compliant with the GDPR notice requirements and section 4 of the application be updated to refer to the privacy notice being published within “one month” of receipt of data. 5. To clarify the wording of the special condition ‘The Nuffield Trust shall ensure access to data disseminated with NHS Digital is strictly prohibited and must not be accessed by Wavex Technology’
2.3	<p><u>University of Sheffield: MR1466 – Life and Bladder Cancer: The Yorkshire Cancer Research Bladder Cancer Patient Reported Outcomes Survey (Longitudinal Study) (Presenter: Dave Cronin) NIC-194387-K3H5K</u></p> <p>Application: This was a new application for Medical Research Information Service (MRIS) list clean for the Life and Bladder Cancer Longitudinal Study. The treatment of bladder cancer can affect the physical, psychological and sexual function of a patient, little is known about the impact of the disease and its treatment upon the overall health related quality of life of individuals.</p> <p>The application was been previously considered on the 22nd February 2018 when IGARD had recommended that the application be processed as two separate applications (cross-sectional and longitudinal). This application was for the longitudinal cohort.</p> <p>Discussion: IGARD noted that the consent given by research subjects appeared to be incompatible with the proposed processing and that consideration should be given to seeking section 251 support for the proposed list clean.</p> <p>IGARD queried whether the applicant was ensuring that only postal addresses be sought for those research participants who elected to provide a postal address when first taking part in the study and asked for further clarification.</p> <p>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.</p> <p>IGARD also noted that the abstract and supporting narrative should be updated with the Article 9 GDPR legal basis.</p> <p>IGARD noted that NHS Digital had included within the abstract the applicant’s legal basis under the General Data Protection Regulation (GDPR) Article 9, however IGARD suggested that the legal basis under Article 9 be updated including supporting narrative</p> <p>Although this application was for the longitudinal study, IGARD noted that the abstract should clearly state that the legal basis for the cross-sectional cohort is both s.251 and GDPR.</p> <p>Outcome: IGARD were unable to make a formal recommendation as there was not a quorum of members able to comment on the application.</p> <p>The following comments were made:</p> <ol style="list-style-type: none"> 1. The consent given by the research subjects in the materials provided appeared to be incompatible with the proposed processing and the applicant may wish to consider seeking section 251 support for the proposed list clean. 2. The applicant should ensure that postal addresses would only be sought for those research participants who elected to provide a postal address when first taking part in the study. 3. To produce a GDPR-compliant privacy notice 4. To update the abstract sections on Article 9 of GDPR to reflect recent discussions between NHS Digital and IGARD

	<p>5. e.</p> <p>6. To update the abstract to clearly state that the legal basis for the cross- sectional cohort is both S251 and GDPR.</p>
2.4	<p><u>University College London (UCL): Precision in Provision: Predicting Treatment Outcome and Resource Use in Child Mental Health. (Presenter: Kimberley Watson) NIC-140981-R5N6Z</u></p> <p>Application: This was a new application for pseudonymised Mental Health Services Data Set (MHSDS) data extract for use in child and adolescent mental health in children and young people aged 2 to 25. There is a lack of evidence about which characteristics of a young person are associated with treatment outcome and resource use and this research aims to address this gap and thereby expand the use of data resources for mental health research whilst at the same time develop the skills base in data linkage.</p> <p>Discussion: IGARD noted that the University College London have published an explicit policy stating that ethics approval is required when dealing with children and young people and suggested that NHS Digital refer to this and clarify with the applicant.</p> <p>IGARD noted that in supporting document 1, the HRA Ethics Tool, the applicant answered “no” to question set 2 and asked for further clarity on the reason for this answer.</p> <p>IGARD queried if the individuals accessing the data had 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.</p> <p>IGARD noted that it was not clear if funding was in place and suggested that the application be updated to clearly state that funding was still in place for the duration of the project outlined in the application / and provide evidence such as a funding letter.</p> <p>IGARD queried whether filters with regard to the age of the cohort are applied, as the research concerns children and young people aged 2-25. IGARD suggested that the data minimisation table in section 3(b) should be updated to clearly outline the filters applied, to reflect the study outlined in the application.</p> <p>IGARD asked for further clarity as to the secondary purpose including confirmation that this is not a separate project and that no other parties are involved; the linkages to be undertaken and the context and purpose of the linkage.</p> <p>IGARD requested that section 4 Fair Processing be updated to read: “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 compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month”.</p> <p>IGARD suggested the applicant work with NHS Digital to amend their current privacy notice including amending misleading statements referencing anonymised data and informed consent being different to consent under GDPR.</p> <p>Outcome: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> 1. NHS Digital to refer to an explicit policy on the University College London website that clearly states that ethics approval is required when dealing with children and young people, and suggested NHS Digital clarify this with the applicant. 2. Explanation of the answer of “no” to the question in question set 2 of the HRA Ethics Tool.

	<ol style="list-style-type: none"> 3. Confirmation within section 5 of the application that the individuals accessing the data have 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. 4. The application should be amended to confirm that funding is in place and provide relevant evidence. 5. The data minimisation table in section 3(b) should be updated to clearly outline the filters applied to reflect the study outlined within the application 6. To provide further clarity with regard to the secondary purpose including confirmation this is not a separate project and no other parties are involved, the linkages to be undertaken and the context and purpose of linkage. 7. To update 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 compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month". 8. The applicant should work with NHS Digital on a fair processing notice that is GDPR compliant including; providing a privacy notice outlining the project and removing misleading statements referencing anonymised data and informed consent being different to consent under GDPR.
2.5	<p><u>NHS North and East London Commissioning Support Unit: NIC-371243-H1P5T (Presenter: Rachel Farrand) NIC-371243-H1P5T</u></p> <p>Application: This was a renewal application for pseudonymised Diagnostic Imaging Dataset (DIDs) extract and Hospital Episode Statistics (HES) data to provide support to Clinical Commissioning Groups (CCGs), other commissioning bodies and Local Authorities to meet their statutory duties under the Health and Social Care Act 2012, and to support NHS health economy wide transformation projects. The data will allow complex and detailed modelling and benchmarking of activity and diagnostic interventions, essential to successful commissioning of services and contract monitoring, including analysing relationships and influences between A&E, inpatient and outpatient care and use of diagnostic services.</p> <p>NHS Digital advised that an audit has been requested to take place within four months.</p> <p>Discussion: IGARD suggested that the first special condition <i>"A maximum of ten years data will be retained at any point, such that as each new data year is received, the oldest year will be deleted e.g. the 2007/08 data year will be deleted once the final complete 2017/18 data year has been received. The CSU will securely destroy the year's data within six weeks of receiving the latest annual dataset and provide a data destruction certificate to NHS Digital"</i> should also be included in section 5(b).</p> <p>IGARD queried why the applicant was requesting national dataset and asked for a clear rationale for this to be included within section 5 of the application.</p> <p>IGARD noted that the incorrect GDPR legal basis was noted in the abstract and asked for this to be amended to 9(2)(H).</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To ensure special condition 1 is also included in section 5(b). 2. To provide a clearer rationale within section 5 for the national dataset requested (for example by reference to the NHS England support).

	3. To correct the abstract section to refer to Article 9(2)(h) GDPR.
2.6	<p><u>Royal Brompton and Harefield NHS Trust: Epidemiology and Prognosis in Acute Myocarditis (Presenter: Rachel Farrand) NIC-144568-D7G6V</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data linked to Office for National Statistics (ONS) mortality data. There is a public interest in sudden cardiac deaths and cardiac transplantation amongst young individuals and a need to update the understanding of the epidemiology and prognosis of myocarditis. Early detection through improved awareness would make a significant contribution to individual patient care.</p> <p>The application was been previously considered on the 9th August 2018 when IGARD had deferred making a recommendation pending; justification of the number of years and volume of national data requested; justification of the wide age range of national data requested; Further detail in section 5(c) about the routes to dissemination to wider stakeholders outside academic activity; explanation in 5(d) as to how national clinical guidelines will be informed by this piece of work; to update section 4 with the standard wording; remove reference to ‘anonymised’ data in paragraph 4, page 7 of the application; remove the ONS terms and conditions; explanation of the answer of “no” to the question in bullet one, question set 2 of the HRA Ethics Tool and further information on funding from the “Alexander Jansen Foundation”.</p> <p>NHS Digital noted that point 4 in the abstract refers to section 5(d) being updated, and that this this needed to be amended to reference 5c.</p> <p>Discussion: IGARD commended the efforts made to revise the application since the last review but queried why the inclusion of all myocardial infarction and cardiac arrest events were being requested and requested a clear rationale for this or to minimise the data requested for those events, for example, filtered by age.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To provide a clearer rationale for the inclusion of all myocardial infarction and cardiac arrest events or to minimise the data requested for those events, for example, filtered by age. <p>It was agreed the condition would be approved OOC by IGARD Members.</p>
2.7	<p><u>NHS Hastings and Rother CCG: DSfC – NHS Hastings and Rother CCG – RS & IV (Presenter: James Humphries-Hart) NIC-91825-W4M1H</u></p> <p>Application: The application had previously been presented to IGARD on the 24 August 2017 and IGARD had recommended for approval subject to conditions: The CCGs (other than Hardwick CCG) should update their privacy notices in line with NHS Digital’s nine criteria, in particular ensuring to use accessible language, be clear who data will be shared with, describe the involvement of Optum as a data processor, ensure that all website links are functioning and ensure not to conflate opting out with patient consent in a way that could be misleading.</p> <p>NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 24th August 2017 and re-reviewed as per usual process.</p> <p>Discussion: IGARD noted that NHS Digital had included within the abstract and section 3 the applicant’s legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, but noted that s5(a) referred only to s.251 and suggested this reference to s.251 be removed from section 5(a). IGARD noted that one of the special conditions refers to “from 25 May 2018” and asked that this be amended or removed.</p> <p>IGARD recognised the work the CCG had undertaken to update their fair processing notice however it was noted the applicant should provide a fair processing notice that it is compliant</p>

	<p>with the notice requirements under the GDPR and suggested that they work with NHS Digital to amend their current privacy notice including being accessible and transparent.</p> <p>Outcome: recommendation to approve for 3 months</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 2. To update section 5 to remove the reference to s251. To remove or amend the special condition that refers to "From 25 May 2018..." <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including being accessible and transparent. <p>It was the view of IGARD that this application would not be appropriate for renewal by Director / IAO delegated authority and IGARD would wish to review this application again when it comes up for renewal</p>
2.8	<p><u>NHS High Weald Lewes Havens CCG: DSfC – NHS High Weald Lewes Havens CCG – RS & IV (Presenter: James Humphries-Hart) NIC-91827-P6J6X</u></p> <p>Application: The application had previously been presented to IGARD on the 24 August 2017 and IGARD had recommended for approval subject to conditions: The CCGs (other than Hardwick CCG) should update their privacy notices in line with NHS Digital's nine criteria, in particular ensuring to use accessible language, be clear who data will be shared with, describe the involvement of Optum as a data processor, ensure that all website links are functioning and ensure not to conflate opting out with patient consent in a way that could be misleading. This should be confirmed by a senior member of NHS Digital staff with appropriate IG expertise.</p> <p>NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 24th August 2017 and re-reviewed as per usual process.</p> <p>Discussion: IGARD noted that NHS Digital had included within the abstract and section 3 the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, but noted that s5(a) referred only to s.251 and suggested this reference to s.251 be removed from section 5(a). IGARD noted that one of the special conditions refers to "from 25 May 2018" and asked that this be amended or removed.</p> <p>IGARD recognised the work the CCG had undertaken to update their fair processing notice however it was 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 being accessible and transparent.</p> <p>Outcome: recommendation to approve for 3 months</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 2. To update section 5 to remove the reference to s251. To remove or amend the special condition that refers to "From 25 May 2018..." <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including being accessible and transparent. <p>It was the view of IGARD that this application would not be appropriate for renewal by Director / IAO delegated authority and IGARD would wish to review this application again when it comes up for renewal</p>

<p>2.9</p>	<p><u>NHS Coastal West Sussex CCG: DSfC – NHS Coastal West Sussex CCG – RS & IV (Presenter: James Humphries-Hart) NIC-91799-G0T9X</u></p> <p>Application: The application had previously been presented to IGARD on the 24 August 2017 and IGARD had recommended for approval subject to conditions: The CCGs (other than Hardwick CCG) should update their privacy notices in line with NHS Digital's nine criteria, in particular ensuring to use accessible language, be clear who data will be shared with, describe the involvement of Optum as a data processor, ensure that all website links are functioning and ensure not to conflate opting out with patient consent in a way that could be misleading. This should be confirmed by a senior member of NHS Digital staff with appropriate IG expertise.</p> <p>NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 24th August 2017 and re-reviewed as per usual process.</p> <p>Discussion: IGARD noted that NHS Digital had included within the abstract and section 3 the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, but noted that s5(a) referred only to s.251 and suggested this reference to s.251 be removed from section 5(a).</p> <p>IGARD noted that one of the special conditions refers to "from 25 May 2018" and asked that this be amended or removed.</p> <p>IGARD recognised the work the CCG had undertaken to update their fair processing notice however it was 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 being accessible and transparent.</p> <p>Outcome: recommendation to approve for 3 months</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5 to remove the reference to s251 2. To remove or amend the special condition that refers to "From 25 May 2018..." <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including being accessible and transparent. <p>It was the view of IGARD that this application would not be appropriate for renewal by Director / IAO delegated authority and IGARD would wish to review this application again when it comes up for renewal</p>
<p>2.10</p>	<p><u>NHS Eastbourne, Hailsham and Seaford CCG: DSfC - NHS Eastbourne, Hailsham and Seaford CCG – RS & IV (Presenter: James Humphries-Hart) NIC-91866-V4R5J</u></p> <p>Application: The application had previously been presented to IGARD on the 24 August 2017 and IGARD had recommended for approval subject to conditions: The CCGs (other than Hardwick CCG) should update their privacy notices in line with NHS Digital's nine criteria, in particular ensuring to use accessible language, be clear who data will be shared with, describe the involvement of Optum as a data processor, ensure that all website links are functioning and ensure not to conflate opting out with patient consent in a way that could be misleading. This should be confirmed by a senior member of NHS Digital staff with appropriate IG expertise.</p> <p>NHS Digital advised that the conditions had not been met within the 3 months following the meeting on the 24th August 2017 and re-reviewed as per usual process.</p>

	<p>Discussion: IGARD noted that NHS Digital had included within the abstract and section 3 the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, but noted that s5(a) referred only to s.251 and suggested this reference to s.251 be removed from section 5(a).</p> <p>IGARD noted that one of the special conditions refers to "from 25 May 2018" and asked that this be amended or removed.</p> <p>IGARD recognised the work the CCG had undertaken to update their fair processing notice however it was 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 being accessible and transparent.</p> <p>Outcome: recommendation to approve for 3 months</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5 to remove the reference to s251. 2. To remove or amend the special condition that refers to "From 25 May 2018..." <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. The applicant should work with NHS Digital on a fair processing notice which is GDPR compliant including being accessible and transparent. <p>It was the view of IGARD that this application would not be appropriate for renewal by Director / IAO delegated authority and IGARD would wish to review this application again when it comes up for renewal</p>
2.11	<p><u>NHS Great Yarmouth and Waveney CCG: DSfC - NHS Great Yarmouth and Waveney CCG – RS (Presenter: James Humphries-Hart) NIC-185897-R6T5S</u></p> <p>Application: This was a new application for identifiable Secondary Use Service (SUS) for Commissioners data covering Risk Stratification (RS) which is a tool for identifying and predicting which patients are at a high risk or are likely to be at high risk and prioritising the management of their care.</p> <p>Discussion: IGARD noted that NHS Digital had included within the abstract and section 3 the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, but noted that s5(a) referred only to s.251 and suggested this reference to s.251 be removed from section 5(a).</p> <p>IGARD noted that one of the special conditions refers to the "25 May 2018" and asked that this be amended or removed.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5 to remove the reference to s251. 2. To remove or amend the special condition that refers to "From 25 May 2018..."
2.12	<p><u>NHS Lincolnshire East CCG: DSfC - NHS Lincolnshire East CCG – IV (Presenter: James Humphries-Hart) NIC-147936-X6M4N</u></p> <p>Application: This was a new application identifiable Secondary Use Service (SUS) for Commissioners data covering invoice validation (IV) which is part of a process by which providers of care or services are paid for the work they do.</p>

	<p>NHS Digital advised that supporting document 11, a supporting letter from CAG was not included in the pack and needs adding.</p> <p>Discussion: IGARD noted that NHS Digital had included within the abstract and section 3 the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, but noted that s5(a) referred only to s.251 and suggested this reference to s.251 be removed from section 5(a).</p> <p>IGARD noted that one of the special conditions refers to the "25 May 2018" and asked that this be amended or removed.</p> <p>IGARD noted that supporting document 1, the data flow diagram was incorrect and advised that the reference to Type 2 objections, along with the red data flow line needed removing.</p> <p>IGARD also noted that the 'Patients Objections' in section 3(c) needed amending to correctly note that Type 2 objections will not apply.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To provide evidence of CAG support <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update section 5 to remove the reference to s251. 2. To remove or amend the special condition that refers to "From 25th May 2018, the Data Protection (charges and information) Regulations 2018..." 3. To update the supporting document 1, the data flow diagram to remove reference to type 2 objections and amend the red data flow line which refers to type 2 objections. 4. To update section 3(c) 'Patient Objections' to correctly note that Type 2 objections will not be applied. <p>It was agreed that the condition would be approved OOC by the IGARD Chair.</p>
2.13	<p><u>Group 195 CCG's – CSDS: Amendment for 195 CCG's to receive Community Services Data Set (CSDS) (Presenter Katharine Robbins / Sharon Thandie / James Humphries Hart)</u></p> <p>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.</p> <p>The briefing paper and application was been previously considered on the 2nd August 2018 when IGARD had deferred making a recommendation pending; (Briefing Paper): 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; 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; the CSDS fair processing notice to be amended to meet NHS Digital's fair processing criteria and is GDPR compliant and (Application): 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; 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 and to include in the application the fair processing section explaining how the data controllers meet their notice requirements under the GDPR.</p>

	<p>Discussion: IGARD noted the efforts made to revise the application but requested that some further minor amendments were made to improve the readability, from a lay perspective, of the introductory paragraphs of section 5.</p> <p>NHS Digital noted that CSDS Fair Processing material had been drafted but not published or included in supporting documents to the revised application. IGARD requested that an updated copy of CSDS privacy notice be provided, and as requested previously, that meets the requirements under GDPR and updated as per comments raised when presented on the 2nd August 2018..</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ul style="list-style-type: none"> NHS Digital to provide a fair processing notice that is compliant with the transparency requirements under the GDPR. <p>It was agreed that the condition would be approved OOC by IGARD Members</p>
2.14	<p><u>Imperial College London: Airwave Health Monitoring Study (MR837) (Presenter: Louise Dunn) NIC-148056-T6T5Z</u></p> <p>Application: This was an amendment and renewal request for Medical Research Information Service (MRIS) data. The study was established to evaluate possible health risks associated with the terrestrial trunked radio (TETRA), a digital communication system used by the police forces and other emergency services. The aim is to estimate the risks of all cancers, certain mortality outcomes and various non-fatal, non-malignant health disorders in relation to airwave use.</p> <p>Discussion: IGARD queried the purpose including whether any different actors are involved and asked for this to be clarified in the application, particularly if there any changes from the existing purpose including whether different actors were involved</p> <p>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".</p> <p>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". The consent materials were discussed, and it was agreed with NHS Digital that, on balance, the proposed processing was not incompatible with the consent materials.</p> <p>IGARD asked for further clarification as to which identifier the applicant is intending to share and confirmation that no clinical data is being shared with NHS Wales Information Service (NWIS) and asked for this to be explicitly stated in sections 3 and 5 of the application.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> To provide further clarity with regard to the purpose (particularly, if relevant, how there is any change from the existing purpose), including whether different actors are involved. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> To update 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

	<p>compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 1 month”.</p> <ol style="list-style-type: none"> 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”. To explicitly state in sections 3 and 5 which identifiers the applicant is intending to share and that no clinical data is being shared with NWIS. <p>It was agreed that the conditions would be approved OOC by IGARD Members</p>
2.15	<p><u>Imperial College London: SAHSU annual renewal and amendment – HES (Presenter: Louise Dunn) NIC-204903-P1J7Q</u></p> <p>Application: This was an amendment and renewal application for identifiable Hospital Episode Statistics (HES) and access to identifiable Civil Registration Data.</p> <p>The Small Area Health Statistics Unit (SAHSU) is a centre of excellence assessing the risk of exposure to environmental pollutants to the health of the population, with an emphasis on the use and interpretation of routine health statistics at small-area level and was established as a recommendation of the Black Enquiry into the incidence of leukaemia and lymphoma in children and young adults near the Windscale / Sellafield nuclear power plant.</p> <p>Discussion: IGARD asked for further clarity of the involvement of Public Health England (PHE), including an analysis of why PHE were not also considered a data controller.</p> <p>IGARD queried the terminology of ‘user under contract with Imperial’ in section 5(b) and asked for further clarification of this along with a further explanation of the type of individual or organisation involved.</p> <p>IGARD queried what the rationale was for the frequency of receipt of data and asked for further clarity in section 5.</p> <p>Outcome: Recommendation to defer, pending:</p> <ol style="list-style-type: none"> To clarify the involvement of PHE including analysis as to why they are not considered as data controller. Clarify the terminology of “user under contract with Imperial” and what type of individual or organisation involved. To amend section 5 to clearly address the rationale of the frequency of receipt of data.
3	<p>AOB</p>
3.1	<p>Annual Report</p> <p>Due to the current IGARD transition including work within NHS Digital on standards and precedents, it was agreed that the inaugural annual report would be incorporated into the 2018/19 report. IGARD noted their thanks to the outgoing IGARD Chair for his work on this to date.</p>
3.2	<p>RAG Meeting</p> <p>IGARD noted that an invite had been received for a member to attend the NHS Digital RAG Meeting on the 24 October 2018 and discussions were ongoing to identify if an IGARD member was available to attend.</p>
3.3	<p>HRA Toolkit</p> <p>NHS Digital advised that there was guidance – possibly provided by HRA? – that suggested researchers answer ‘no’ to question set 2 in the HRA Tool in relation to whether ethics approval</p>

	is required, if the research involved pseudonymised data. IGARD requested that they be provided with a copy of this guidance.
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Independent Group Advising on Releases of Data (IGARD): Out of committee report 22/08/18

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-139035-X4B7K (NIC-92346-T4Z0F)	Temporary National Repository	24/05/18	1. 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."	OOC by IGARD Members	Quorum of IGARD Members	N/A

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

- None notified to IGARD