

## Independent Group Advising on the Release of Data (IGARD)

### Minutes of meeting held 5 July 2018

**Members:** Sarah Baalham, Joanne Bailey, Jon Fistein, Kirsty Irvine (Chair), Eve Sariyiannidou.

**In attendance:** Dave Cronin, Rachel Farrand, James Humphries-Hart, Karen Myers, Sharon Thandie, Vicki Williams.

**Apologies:** Anomika Bedi, Chris Carrigan, Nicola Fear

1	<p><b>Declaration of interests</b></p> <p>Joanne Bailey noted a professional link to the commissioning services work being undertaken (Community Services Data Set Briefing Note), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Joanne Bailey noted a professional link to the Chair of the Trust (University of Oxford NIC-135294-P7L0F), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Kirsty Irvine noted professional links to the Royal College of Obstetricians (NIC-44356-Y8N6R), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Jon Fistein noted professional links to HQIP (Royal College of Obstetricians NIC-44356-Y8N6R), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p><b>Review of previous minutes and actions</b></p> <p>The outcomes of the 28 June IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting.</p> <p>The minutes of the 28 June IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings.</p> <p><b>Out of committee recommendations</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<b>Data applications</b>
2.1	<p><u>University of Oxford: The delivery of major trauma care in England - impact and effectiveness following a whole system reorganisation. (Presenter: Dave Cronin) NIC-177392-B8T1Z</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) and Office for National Statistics mortality (ONS) data. The data is required for use in the TRAuma Care Reorganisation (TRACER) Project, which is looking at the clinical and cost-effectiveness of the reorganisation of trauma care services into Regional Trauma Networks (RTNs) and Major Trauma Centres (MTCs).</p> <p>NHS Digital noted that the legal basis under General Data Protection Regulations (GDPR) should be updated to reference 'public interest'</p> <p>NHS Digital noted that the ethics wording within section 7 should be updated.</p> <p>NHS Digital noted that the applicant's privacy notice may need to be updated.</p>

**Discussion:** IGARD welcomed the application and noted the importance of the work being undertaken and that the study was in the public interest to gather evidence on major policy decisions.

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.

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 were unclear about the role of the Trauma Audit & Research Network (TARN) and the legal basis for NHS Digital to receive data from TARN, and that NHS Digital should satisfy itself that any data collected as part of the processing of data had a clear legal basis.

IGARD noted that the applicant had s251 however it was not clear of the arrangements in place and suggested that the abstract be updated to clearly state, since the applicant had applied for s251 under 'service evaluation' rather than research and IGARD had to be guided by HRA CAG. NHS Digital noted that reference to research and published research were clearly articulated in the application, with reports published back to NICE but IGARD noted that if the s251 was for research advice should be sought from HRA CAG by the applicant. It was also suggested that any inaccurate statements referencing s251 be removed from the abstract.

It was also suggested that clarification be sought of the legal basis under GDPR for NHS Digital to receive data from TARN and this be clearly outlined in the abstract. It was also suggested that the data flows outlined in section 3 be consistent with the legal basis outlined within the abstract and also suggested that reference to identifiable data in this section and the abstract be updated to 'pseudonymised data'.

IGARD were not clear of the role and responsibilities of TARN or the University of Manchester within the project and suggested that the roles be clarified within section 5 of the application.

IGARD noted that NIHR funding was in place and queried if this was for the researcher or project. NHS Digital confirmed that the researcher had NIHR funding and IGARD suggested that a clear narrative be given in section 8.

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 the application stated that ethics approval was not required and the application be updated with appropriate standard ethics approval wording within section 7 of the application. IGARD also queried reference to MTC 22 within the organisations listed within section 5c and asked for clarity.

IGARD noted that the applicant had updated their privacy notice and that a new poster had been issued with a link to the study website, however noted that since the poster was part of the patient notification information which HRA CAG reviewed as part of its approval process, that the privacy notice be updated to be compliant with GDPR privacy notice requirements. 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 and additionally, suggested that NHS Digital provide an update to IGARD as to whether the

	<p>applicant had published a GDPR-compliant privacy notice and within 6 weeks after dissemination of the data</p> <p>IGARD queried reference to the Big Health Data Group and if they were part of the University of Oxford. NHS Digital noted that they were a department of the University however it was suggested that confirmation be provided that the Group were a department of the University.</p> <p><b>Outcome:</b> recommendation deferred pending:</p> <ol style="list-style-type: none"> <li>1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD and the processing being undertaken.</li> <li>2. NHS Digital work with the IG Advisor to IGARD to correctly list the DPA 2018 schedule 1 Part 1 references against any Article 9 legal basis cited and clearly describe how the schedule conditions are met.</li> <li>3. To clarify the legal basis under GDPR for NHS Digital to receive the data from the Trauma Audit &amp; Research Network (TARN).</li> <li>4. To clarify the role of TARN and the University of Manchester in the project..</li> <li>5. To update the application to ensure the legal basis stated is consistent with the data flows</li> <li>6. Providing confirmation that the Big Health Data Group are a department of the University of Oxford.</li> <li>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.</li> <li>8. To amend the abstract to accurately describe the s251 arrangements</li> <li>9. To update section 8 to clearly state that it is the researcher who is NIHR funded and not the project outlined within the application</li> <li>10. To clarify reference to "MTC 22" within section 5c</li> <li>11. To complete the ethics approval section of the application to explain why it is not required.</li> <li>12. To remove a reference to 'identifiable data' in the legal basis section and the abstract and replace with 'pseudonymised data'</li> </ol> <p>The following advice was given</p> <ol style="list-style-type: none"> <li>1. 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. Additionally, NHS Digital is requested to provide an update to IGARD as to whether the applicant has published a GDPR-compliant privacy notice. This update to IGARD should be provided within 6 weeks after dissemination of the data.</li> </ol>
2.2	<p><u>University of Oxford: MR1460 - OxValve - Survival following a diagnosis of Valvular Heart Disease in a primary care population (OxValve-Survive). (Presenter: Dave Cronin) NIC-135294-P7L0F</u></p> <p><b>Application:</b> This was a new application for identifiable Medical Research Information Service (MRIS) data. This application was previously submitted for IGARD review on the 14 June 2018 but was withdrawn by the presenter. The purpose of the study is to identify patients with unrecognised heart valve problems in order to study valvular heart disease further and to see how common it is. The secondary purpose is to study what happens to any abnormality of the heart valves over the long term.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance and value of the work being undertaken.</p>

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.

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 reference to NICOR ,and asked for confirmation that there would be no linkage to the NICOR data listed under this application, noting this may be subject to a future application to IGARD.

IGARD noted that supporting documents 4.9 and 5.9 provided with the application required updating and especially if the applicant intended to use the versions provided to IGARD to forward to participants, and agreed to provide detailed comments to NHS Digital to support discussions with the applicant in order to communicate with the cohort and no later than 3 months following the dissemination of the data, including adding the updated information to the study and Trust websites. IGARD noted that the new information provided to participants should be suitable for all types of consent participants have received, noting that participants have signed various consent forms and that a special condition be added to section 6 that the applicant work with NHS Digital to revise and recirculate the patient information leaflets to inform participants about the current processing of their data including the legal basis under GDPR for processing the their data, sharing identifiable data with NHS Digital and the ability to opt out.

It noted that the abstract be updated to remove reference to consent being the legal basis for processing data and that the applicant ensure that website links be provided on both the study and the Trust websites. 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 and additionally, suggested that NHS Digital provide an update to IGARD as to whether the applicant had published a GDPR-compliant privacy notice and within 6 weeks after dissemination of the data

IGARD noted that the cohort size of 4000 and that all participants under this study had been invited to a rescreen. It was noted that the applicant was looking for those with both a negative and positive result in order to check against HES in order to clarify if any other incidents to produce a negative or positive outcome. IGARD suggested that this be clearly outlined in section 5 of the application including confirmation of the cohort size and composition. It was also suggested that the sub study be clearly described in section 5a, for transparency and to ensure the description is accurate.

IGARD also queried reference to "the original OxValve team (at Oxford University Hospitals Trust NHS FT) will not be involved in this process and will have not access to the data in its raw form" and asked for clarification within section 5 of the statement

**Outcome:** recommendation to approve

The following amendments were requested:

	<ol style="list-style-type: none"> <li>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.</li> <li>2. 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.</li> <li>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,</li> <li>4. Confirmation that there will be no linkage to NICOR data under this agreement, even though it may be the subject of a further application and they will not be able to link to data under the application.</li> <li>5. To clarify a statement in the abstract “the original OxValve team (at Oxford University Hospitals Trust NHS FT) will not be involved in this process and will have not access to the data in its raw form”</li> <li>6. To clarify the cohort size and composition</li> <li>7. To include a special condition within section 6 that the applicant work with NHS Digital to revise and recirculate the patient information leaflet to participants to fully inform patients about current processing of their data, including, but not limited to, the legal basis under GDPR for the processing of their data and their ability to opt out</li> <li>8. To update section 5a to correctly describe the sub-study</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that the applicant remove reference to consent being as the legal basis for processing data from their published Privacy Notice and ensure the website links between the study and Trust websites were enabled.</li> <li>2. 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. Additionally, NHS Digital is requested to provide an update to IGARD as to whether the applicant has published a GDPR-compliant privacy notice. This update to IGARD should be provided within 6 weeks after dissemination of the data.</li> </ol>
2.3	<p><u>The Nuffield Trust: Prisoner health: Understanding prisoners’ healthcare needs, their use of healthcare services and quality of care received (Presenter: Dave Cronin) NIC-195377-M9L8Z</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) data. The 'Prisoner Health' project aims to improve understanding of prisoners’ health care needs, their use of health care services and the quality of care received for prisoners compared to the non-prison population.</p> <p>NHS Digital noted that the legal basis under General Data Protection Regulations (GDPR) should be updated to reference ‘public interest’</p> <p>NHS Digital noted that the applicant’s privacy notice may need to be updated.</p> <p><b>Discussion:</b> 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 also suggested that it be clearly articulated within section 5a, in addition to “For the purpose of these legitimate interests, the Nuffield Trust is undertaking the following</p>

<p>study: Prisoner health: Understanding prisoners' healthcare needs, their use of healthcare services and quality of care received" the legitimate interest relied upon and how it relates to the purpose of the research being undertaken, including confirmation within the abstract or as an additional supporting document that NHS Digital have assessed and deemed the Legitimate Interest Assessment (LIA) satisfactory in order to meet its GDPR obligations.</p> <p>IGARD noted that the study was using the prison postcode as a proxy to identify patients in the penal establishment, however for those prisons located in residential areas or for those living on the prison site asked for a clear statement in section 5 that only those in the prison population would be included in the prison postcode. IGARD were also not clear how a control group derived from HES data had been established. NHS Digital noted that the control group was a random subset from the wider population and from data already held by the applicant, however IGARD noted that it was not clear within section 5 who the control cohort were and from what data, and how they were derived from the HES dataset.</p> <p>IGARD also noted that the prison population would be limited to how they access information relating to this study and suggested that a clear statement be included in section 4 of the fair processing undertaken by the applicant to ensure the prison population had access to the study and information. 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 and additionally, suggested that NHS Digital provide an update to IGARD as to whether the applicant had published a GDPR-compliant privacy notice and within 6 weeks after dissemination of the data</p> <p>IGARD noted that the Health Foundation was listed as a funder for the study within section 5e of the application and suggested that section 8b be updated to list the Health foundation as the source of funding.</p> <p>IGARD noted that Data Protect UK were listed as a storage location and that a statement in section 5b noted "the Nuffield Trust shall ensure access to data disseminated by NHS Digital is strictly prohibited and must not be accessed by the Trust's IT Manged Provider" and suggested that a clear statement be given in the application that there would be no processing or storage of data by 3<sup>rd</sup> parties including a clear explanation of 'managed IT services'.</p> <p><b>Outcome:</b> unable to recommend for approval</p> <ol style="list-style-type: none"> <li>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</li> <li>2. To clearly state at the start of section 5a the legitimate interest relied upon, as related to the purpose of the research</li> <li>3. Confirmation in the abstract or a supporting document that NHS Digital have assessed the LIA and deemed it satisfactory.</li> <li>4. If The Health Foundation is a funder, to update the source of funding in section 8b to reference that entity.</li> <li>5. Clarification of the control cohort, including a clearer description of who they are and from what data they how there are derived from the HES data.</li> <li>6. To clearly state in section 5 that the prison postcode will include only the prison population and not those working in the prison or residential properties in close proximity.</li> <li>7. Giving a clear explanation within section 5 the roles and responsibilities of the IT infrastructure outlined within the application, including any access to data.</li> </ol>
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	<p>8. To clearly state within section 4 the steps undertaken to inform the prison population of the study and how they can access the information.</p> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. 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. Additionally, NHS Digital is requested to provide an update to IGARD as to whether the applicant has published a GDPR-compliant privacy notice. This update to IGARD should be provided within 6 weeks after dissemination of the data.</li> </ol>
2.4	<p><u>University of Essex: Evaluating the effects of Community Treatment Orders (CTO) in England (Presenter: Rachel Farrand) NIC-07360-K4R9R</u></p> <p><b>Application:</b> This is an extension application for pseudonymised Hospital Episode Statistics (HES) data, Office for National Statistics mortality (ONS) data and Mental Health Minimum Data Set for use in a project aiming to address the need of evidence of Community Treatment orders in different clinical and social circumstances answering calls from the Care Quality Commission (CQC) and House of Commons Health Committee for research into this issue.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the importance of the study.</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 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.</p> <p>IGARD noted that the individual researchers accessing the data were employees of various collaborating universities, specifically University of Portsmouth, Ulster University, the University of Warwick and the University of Southampton and suggested that it be explicitly stated in section 5 how the collaborating universities were involved, including their role in the design and performance of the project, the legal basis for each individual researcher to access the data and to clarify if the universities had access to the data. IGARD also requested sight of the collaboration agreement in place between the collaborating organisations.</p> <p>IGARD subsequently queried why the collaborating universities (outlined above) were not listed as joint Data Controllers, alongside ONS and the University of Southampton, which would be dependent on their involvement in the design and performance of study, including any access to data, as outlined in the application.</p> <p>IGARD queried the researchers listed in supporting document 7, Micro Release Panel (MRP) approval, and that one of the researchers, Sam Wilding, was not listed. NHS Digital noted that a separate supporting document was provided at 'SD11', however it noted that this researcher was not amongst the names listed on supporting document 7 and that evidence of the Approved Researcher (AR) was required for this application.</p> <p>IGARD noted within section 5c that the applicant had referenced 'the intention is to maximise the potential impact and societal benefits of research...' and that NHS Digital may wish to consider this as a good practice statement for applications.</p> <p>IGARD noted that the applicant's Data Sharing Agreement with NHS Digital was due to expire, and in light of this it was suggested that NHS Digital might wish to consider a short term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.</p>

	<p><b>Outcome:</b> recommendation deferred pending:</p> <ol style="list-style-type: none"> <li>1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD</li> <li>2. To provide a copy of the collaboration agreement and update section 5 to be explicit how the collaborators outlined in the application are involved, including their role in the design and performance of the project and any data they may have access to.</li> <li>3. To clarify which organisations perform ‘data controller’ functions depending on their involvement in the design and performance of the project and any data they may have access to.</li> <li>4. To provide documentary evidence that the MRP status is active for approved researcher Sam Wilding.</li> </ol>
2.5	<p><u>University of Essex: Improving the experience of dementia and enhancing active life: living well with dementia – the IDEAL study (Data linkage extension) MR1461 (Presenter: Rachel Farrand) NIC-29822-NON7W</u></p> <p><b>Application:</b> This was a new application requesting access to Hospital Episode Statistics (HES) and Mental Health Data linked to Office for National Statistics (ONS) mortality data (including date of death) for a consented cohort of approximately 900 participants (a subset of the originally recruited cohort, which included people with dementia and their carers). This application was previously submitted to IGARD on 21 June 2018 but was deferred pending the update of Article 6 and 9 of GDPR; clarification that the personal consultee or nominated consultee advice document(s) is available; updating of Section 5 to clarify the role of University of Cardiff; clarifying that ONS and University of Southampton are Data Controllers who also process data; clarification within section 5 of who is responsible for the actions of the individual researchers and amendment of the abstract to correctly list the legal basis reflected in the table in section 3.</p> <p>NHS Digital noted that the application was submitted similar requests for Welsh and Scottish data and confirmed that the English data would be considered alongside but would not be linked.</p> <p><b>Discussion:</b> 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.</p> <p>IGARD noted that the individual researchers accessing the data were employees of various collaborating organisations, specifically the University of Exeter and the London School of Economics and Political Science and suggested that it be explicitly stated in section 5 how the collaborating organisations were involved, including their role in the design and performance of the project, the legal basis for each to access the data and to clarify if the organisations had access to the data. IGARD also requested sight of the collaboration agreement in place between the collaborating organisations.</p> <p>IGARD subsequently queried why the collaborating organisations (outlined above) were not listed as joint Data Controllers, alongside ONS and the University of Southampton, which would be dependent on their involvement in the design and performance of study, including any access to data, as outlined in the application.</p> <p>IGARD queried the researchers listed in supporting document 7 ‘ethics approval’ and that legal justification be provided in writing why the researchers listed in section 9 of the application are covered by consent and why evidence of the Approved Researcher (AR) status is not required</p>



	<p>for this application. IGARD noted that this was a standard requirement of other applications presented to IGARD.</p> <p>IGARD also suggested that the abstract be updated to amend references to common law duty of confidentiality and patient consent to: "NHS Digital has determined that the processing in this application is likely to be within the reasonable expectations to those that have consented".</p> <p>IGARD noted that the applicant had updated the privacy notice in line with GDPR requirements and suggested that this be disseminated to participants with the next iteration of the newsletter.</p> <p><b>Outcome:</b> recommendation deferred pending:</p> <ol style="list-style-type: none"> <li>1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD</li> <li>2. To provide a copy of the collaboration agreement and update section 5 to be explicit how the collaborators outlined in the application are involved, including their role in the design and performance of the project and any data they may have access to.</li> <li>3. To clarify which organisations perform 'data controller' functions depending on their involvement in the design and performance of the project and any data they may have access to.</li> <li>4. NHS Digital to provide in writing the legal justification why the researchers listed in section 9 are covered by consent and why evidence of AR status is not required under this application, while it is a standard requirement in other applications.</li> <li>5. To update the abstract to amend references to patient consent and common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is likely to be within the reasonable expectations to those that have consented"</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that the updated Privacy Notice be disseminated to participants with the next iteration of the newsletter.</li> </ol>
2.6	<p><u>York University: Life Limiting conditions in children and young people in England: Prevalence and Survival (Presenter: Dickie Langley) NIC-379681-D6L7G</u></p> <p><b>Application:</b> This was an amendment application for pseudonymised Hospital Episode Statistics (HES) and Office for National Statistics (ONS) data. The purpose of the study is to look at the survival of children and young people with life-limiting conditions to fully investigate the current and future needs of this population.</p> <p><b>Discussion:</b> IGARD welcomed the application and noted the good work being undertaken by this study.</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 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</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 and additionally, suggested that NHS Digital provide an update to IGARD as to whether the applicant had published a GDPR-compliant privacy notice and within 6 weeks after dissemination of the data</p> <p>IGARD queried if any yielded benefits had been generated, noting that the previous application had been presented to DAAG in 2016. IGARD suggested that additional measurable benefits</p>

	<p>be included within section 5 along with additional yielded benefits with a clear timescale for outputs, for transparency.</p> <p>IGARD noted that the pseudonymised date of death data was linked to HES data and although noted that it is not classed as a direct identifier suggested that a risk assessment be undertaken to clarify, noting that risk assessment should be undertaken by NHS Digital on a case by case basis.</p> <p>IGARD noted that the Micro Release Panel (MRP) information provided at supporting documents 7 and 8 were not presented as an email trail and that IGARD would expect to see evidence that the MRP approval was in place.</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD</li> <li>2. To provide a copy of the risk assessment undertaken explaining why Date of Death is classed as pseudonymised in this application, since it is linked to HES data.</li> <li>3. To provide documentary evidence that the MRP status is active.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To provide more examples of measurable and yielded benefits within section 5 of the application with a clear timescale for outputs.</li> </ol> <p>The following advice was given</p> <ol style="list-style-type: none"> <li>1. 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. Additionally, NHS Digital is requested to provide an update to IGARD as to whether the applicant has published a GDPR-compliant privacy notice. This update to IGARD should be provided within 6 weeks after dissemination of the data.</li> </ol> <p>It was agreed the conditions would be approved OOC by the IGARD chair</p>
2.7	<p><u>Royal College of Obstetricians and Gynaecologists: NMPA-HES-ONS-MSDS Linked Dataset (Presenter: Dickie Langley) NIC-44356-Y8N6R</u></p> <p><b>Application:</b> This was an amendment application for pseudonymised Hospital Episode Statistics (HES) data and identifiable Office for National Statistics mortality (ONS) data. The purpose is for the Healthcare Quality Improvement Partnership (HQIP), National Clinical Audit and Patients Outcomes Programme's National Maternity and Perinatal Audit (NMPA). The aim of the audit is deliver a clinically meaningful and methodologically robust audit of NHS maternity services.</p> <p><b>Discussion:</b> 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.</p> <p>The application noted this was a renewal of HES data and an amendment to request linked ONS data for the cohort, however IGARD stated that the application be updated to clearly state that ONS mortality data was being requested as part of this application, which would accurately reflect section 3b.</p>

	<p>IGARD suggested that section 5 of the application be updated to clearly reference that the data was both pseudonymised and identifiable, as outlined in section 3.</p> <p>IGARD noted that the application stated that ethics approval was not required, however since ethics approval is in fact required for this application that the application be updated with appropriate standard ethics approval wording within section 7 of the application.</p> <p>IGARD suggested that previous summary iterations within the abstract were not relevant to this application and for transparency suggested that they be removed.</p> <p>IGARD noted that the special condition in section 6 relating to 'data destruction' be removed since the applicant was not going to destroy data already held since it was not relevant to this application.</p> <p>IGARD noted that all Data Controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period following dissemination of data</p> <p><b>Outcome:</b> recommendation deferred pending:</p> <ol style="list-style-type: none"> <li>1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD</li> <li>2. To update the application to clearly state that ONS data is being requested as part of this application</li> <li>3. To amend reference to all data being both pseudonymised and identifiable within section 5a of the application.</li> <li>4. To include the standard ethics approval wording within the application.</li> <li>5. The special condition wording in section 6 reference 'data destruction' should be removed since it is not relevant to this application.</li> <li>6. To update the abstract to remove reference to previous summary iterations</li> </ol>
2.8	<p><u>CRAB Clinical Informatics: HES res-supply CRAB Clinical Informatics (Presenter: Rachel Farrand) NIC-351722-W7D4N</u></p> <p><b>Application:</b> This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data. Copeland Risk Adjusted Barometer (CRAB) is a web-based tool to evaluate quality and outcomes in a way which accurately reflects the clinical profile of patients treated. This is designed to provide a granular local dashboard to support NHS Trusts and appropriate National Authorities to interpret mortality analysis and understand safety in relation to avoidable harm, morbidity and areas for improvement.</p> <p><b>Discussion:</b> IGARD noted the steps undertaken by the applicant to address their legal basis under GDPR and welcomed their commentary with regard to statutory government purposes. It was 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.</p> <p>IGARD also suggested that it be also be clearly outlined at the start of section 5a the legitimate interest relied upon as related to the purpose of the research, including confirmation within the abstract or as an additional supporting document that NHS Digital have assessed and deemed the Legitimate Interest Assessment (LIA) satisfactory in order to meet its GDPR obligations, noting that it was not compulsory to complete a LIA but that it would provide information on what they are doing since they did not appear to have a published privacy notice.</p>

It was therefore 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 comply with GDPR, including being published and accessible.

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 within section 5a that the applicant may provide a granular local dashboard to help NHS Trusts and appropriate National Authorities, however it was suggested that reference to other national bodies be removed since it was not part of this application. IGARD also suggested that NHS Digital may wish to work with the applicant to narrow the application to their current sole customer to focus the application to its current purpose and data requested, and further suggested that the data fields in section 3b be limited further to align to the current project outlined or to clarify why they cannot be limited further.

It was noted that the CQC were accessing record level data and queried if they should be a Data Processor, since the CQC would usually access tabulated / aggregated data and asked for clarification. IGARD queried reference to 'raw data' within section 5a and 5b of the application and that this data was being stored on the applicant's server. NHS Digital noted that the data was stored on CRAB Clinical Informatics server but that they would not be processing the data, however IGARD suggested that it be explicit that only L2S2 Limited would access the raw data and CRAB Clinical Informatics cannot access this raw data.

**Outcome:** recommendation deferred pending:

1. To update the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD and the processing being undertaken.
2. Confirmation in the abstract or a supporting document that NHS Digital have assessed the LIA and deemed it satisfactory.
3. CRAB Clinical Informatics to provide a fair processing notice and to ensure that it is compliant with the notice requirements under the GDPR.
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. To remove reference to other 'national bodies' since they are not relevant to this application
6. To clarify why the CQC are not listed as a Data Processor
7. To clarify that only the Data Processor, L2S2 Limited, will have access to the raw data and that CRAB Clinical Informatics who own the server cannot access this raw data.
8. To clarify why the data fields outlined in section 3b cannot be limited further to align to the project outlined in the application

The following advice was given:

1. IGARD suggested that NHS Digital work with the applicant to narrow the application to their current sole customer: CQC.

IGARD noted the importance of the research undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, and in light of this it was suggested that NHS Digital might wish to consider a short term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.

2.9	<p><u>Community Services Data Set (CSDS) Briefing Note (Presenter: Sharon Thandie / James Humphries-Hart)</u></p> <p>The briefing note was to inform IGARD of an extension to the Children's and Young People Health Services (CYPHS) Dataset, to include data on all ages, and now referred to as the Community Services Dataset (CSDS). The CSDS expands the scope of the existing CYPHS, by removing the 0-19 age restriction.</p> <p>IGARD was overall supportive of the service. It raised a number of substantive issues with regard to the proposed approach and it was agreed that these would be explored further.</p>
2.10	<p><u>Group 207 CCG's – CSDS: Amendment for 207 CCG's to receive Community Services Data Set (CSDS) (Presenter: Sharon Thandie / James Humphries-Hart)</u></p> <p><b>Application:</b> This is an extension application for pseudonymised Community Services Data Set (CSDS). This is to expand the scope of the existing Children and Young People Health Service (CYPHS), by removing the 0-19 age restriction.</p> <p><b>Discussion:</b> IGARD welcomed the application which came for advice on the legal basis to disseminate data and without prejudice to any additional issues that may arise when the application is fully reviewed.</p> <p>IGARD noted a number of substantive issues raised with regard the briefing paper and suggested that the application be updated and resubmitted along with the updated briefing paper.</p> <p><b>Outcome:</b> Following the substantive issues raised with regard the briefing paper, the application was presented to IGARD for advice.</p>
3	<p><b>AOB</b></p> <p><b>Clear Basis in Law wording in relation to UK universities</b></p> <p>To support NHS Digital, it was agreed that IGARD would provide a briefing paper outlining the steps undertaken to provide a clear basis in law for UK University applications to IGARD. It was also noted that the process would also apply to Foundation Trusts undertaking research but with additional commentary.</p> <p><b>Appendix A – summary of open actions</b></p> <p>IGARD members agreed that appendix A would be removed from all future minute's templates, after today's meeting, and that the Secretariat would provide to the meeting an open / close action log. IGARD noted that actions would continue to be reviewed each meeting and comments noted in section 1, where applicable.</p>

## 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	<p>14/09/17: Ongoing. It was agreed this would be discussed during the educational session.</p> <p>07/12/17: Ongoing. It was agreed to bring the first draft to January's education session.</p> <p>08/02/18: it was agreed the updated draft be brought to the March education session</p> <p>01/03/18: the March education session was cancelled, and it was agreed to take the draft annual report to the April education session.</p> <p>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.</p> <p>12/04/18: The Chair noted he was yet to contact external to NHS Digital stakeholders.</p> <p>19/04/18: IGARD chair to update members at May's education session.</p> <p>03/05/18: The Chair of IGARD noted that he would be contacting key stakeholders over the coming weeks.</p> <p>28/06/18: The Deputy Caldicott Guardian had requested an update to the progress of the annual report from Chris Carrigan, the author of the report.</p> <p>05/07/18: The Secretariat had requested sight of the final draft version by 11/07/18 for dissemination in draft to IGARD Members.</p>	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	<p>10/08/17: It was anticipated that a paper on this would be brought to IGARD within the following two weeks.</p> <p>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 continuing to act as a data processor. IGARD welcomed this update and requested written confirmation.</p> <p>31/08/17: IGARD were notified that the requested written confirmation should be provided within one day.</p> <p>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.</p> <p>05/04/18: IGARD Secretariat had contacted Garry Colman and were awaiting a response.</p> <p>28/06/18: IGARD Secretariat had contacted Garry Colman to provide an update and were awaiting a response.</p> <p>05/07/18: ongoing</p>	Open
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	<p>22/02/18: IGARD Secretariat to contact Garry Coleman to suggest presentation at the June education session.</p> <p>05/04/18/18: IGARD Secretariat were awaiting a response.</p> <p>28/06/18: IGARD Secretariat had contacted Garry Colman to provide an update and were awaiting a response.</p> <p>05/07/18: ongoing</p>	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	Garry Coleman	<p>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</p>	Open

	disseminated by NHS Digital would be protected and provide a verbal update to IGARD on the progress of this note by 5 April 2018.		<p>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.</p> <p>26/04/18: IGARD secretariat were awaiting a response following issue of a reminder</p> <p>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.</p> <p>10/05/18: The Director Data Dissemination noted that a briefing note would be provided to IGARD for the 24 May meeting.</p> <p>24/05/18: it was noted that a briefing note had not been provided to IGARD.</p> <p>28/06/18: IGARD Secretariat had contacted Garry Colman to provide an update and progress made in providing IGARD with a briefing note.</p> <p>05/07/18: ongoing</p>	
12/04/18	<p>IGARD Members to consider the HRA guidance on GDPR published on line</p> <p>IGARD Chair to provide feedback to the Caldicott Guardian</p>	<p>IGARD</p> <p>IGARD Chair</p>	<p>19/04/18: IGARD members had considered the HRA guidance and asked the IGARD Chair to provide feedback to the Caldicott Guardian.</p> <p>26/04/18: IGARD Secretariat awaiting comment following issue of a reminder.</p> <p>03/05/18: the Chair of IGARD to provide a copy of the email sent to the Caldicott Guardian to the Secretariat team</p> <p>21/06/18: IGARD Secretariat have chased the Chair for a copy of the email.</p>	Closed



			<p>28/06/18: IGARD Secretariat had contacted Chris Carrigan for a copy of the email in order to disseminate to IGARD Members for information.</p> <p>05/07/18: IGARD noted that the email had been disseminated and it was agreed the action should be closed.</p>	
28/06/18	IGARD asked when the National Data Opt Outs will be upheld by NHS Digital and it was suggested that NHS Digital provide a briefing note, for consideration by IGARD and before they are upheld	Arjun Dhillon / Tim Magor	05/07/18: ongoing	Open
28/06/18	The Deputy Caldicott Guardian to provide an update of the engagement which had taken place with CPRD with regard to measures in place to engage with participating General Practices so that both GP's and CPRD meet with obligations as Data Controllers under GDPR.	Arjun Dhillon	05/07/18: ongoing	Open

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 29/06/18

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-174557-H6J6Y	NHS Rotherham CCG	03.05.18	1. The Fair Processing Notice be amended to meet the NHS Digital nine minimum criteria (to be known as NHS Digital's fair processing criteria) for privacy notices specifically to replace all references to anonymised information and data with de-identified.	IGARD Chair	Interim IGARD Chair	N/A
NIC-58974-T3M1M	University of Essex	17.05.18	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.			To amend the abstract statement to include: "The data are required for research purposes <b>in the public interest...</b> "

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

- None notified to IGARD