

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

### Minutes of meeting held 21 March 2019

**Members:** Anomika Bedi, Maria Clark, Kirsty Irvine (Chair), Priscilla McGuire, Eve Sariyiannidou.

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

**Apologies:** Sarah Baalham, Joanne Bailey, Nicola Fear.

1	<p><b>Declaration of interests:</b></p> <p>There were no declarations of interest.</p> <p><b>Review of previous minutes and actions:</b></p> <p>The minutes of the 14<sup>th</sup> March 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting.</p> <p><b>Out of committee recommendations:</b></p> <p>An out of committee report was received (see Appendix B).</p>
2	<p><b>Data applications</b></p>
2.1	<p><u>The University of Manchester: MR1319 - Childhood Arthritis Prospective Study (CAPS)</u> (Presenter: Rachel Farrand) NIC-292331-J5B5X</p> <p><b>Application:</b> This was a renewal, extension and amendment application for identifiable Medical Research Information Service (MRIS) for a study aiming to identify factors that may be involved in the development of arthritis and to identify factors that may help predict how patients will manage over the long-term. Better understanding of the course of the illness will help in choosing the best treatment for children in the future.</p> <p><b>Discussion:</b> IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed.</p> <p>Advice on revised consent materials:</p> <p>IGARD noted that it was not clear within the consent materials provided that the participants would be reconsented when they turned 16 and asked that the application was updated accordingly to reflect this. IGARD also asked for clarification as to why the applicant was taking the parents' consent on all consent forms for those aged under 16 and to ensure that this reflected current best practice. IGARD also suggested that, in reaching the view on current best practice, seeking the views of, inter alia, the NHS Digital Caldicott Guardian, the National Data Guardian, along with other relevant bodies.</p> <p>IGARD noted that the consent materials referred to 'gender' and suggested that the applicant consider revising this to use the term 'sex' which was consistent with the type of data NHS Digital disseminated.</p> <p>IGARD queried if the revised consent materials were sufficiently detailed and comprehensive enough to cover all the requirements of the research being undertaken or that may be undertaken in the future, and suggested that they were reviewed accordingly.</p> <p>IGARD noted that paragraph 6 (point vi) of the Patient Information Sheet referred to the linking of HES data 'with permission' and asked that this was reviewed and made clear that the</p>

<p>consent being taken covered this use of data and that separate future consent would <b>not</b> be sought.</p> <p>IGARD noted the reference to the Office for National Statistics (ONS) and Public Health England (PHE) collecting data and asked that this was removed as it was not relevant.</p> <p>IGARD noted that the term “anonymised” was used in both the Patient’s Consent Form and the Parent’s Consent Form (Point 10 in both forms) and suggested this was removed and the section amended to state that the child will ‘not directly identified’.</p> <p>IGARD queried the following wording within the Patient Information Sheet “Any personal data used for linkage will be deleted by the CAPS study staff at the University of Manchester...” and asked that the applicant review this element of the wording to try to make the explanation as clear and accurate as possible. IGARD asked whether the applicant intended this paragraph to explain that certain data fields would be deleted/pseudonymised to minimise the likelihood of re-identification and that this activity would occur <b>after</b> linkage has taken place.</p> <p>IGARD queried if the appropriate ethics approval was in place and suggested that the application was updated to reflect this.</p> <p>Advice on the application:</p> <p>IGARD noted that the application required a clear narrative within section 5 (Purpose / Methods / Outputs) that aligned with the consent materials, clarifying whether the cohort would be reconsented when they turned 16.</p> <p>IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: <i>“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 the latest within one month”</i> and of the data being disseminated.</p> <p>IGARD queried if all the previous comments when the application was last reviewed by IGARD on the 20<sup>th</sup> July 2017 had been addressed and asked that this was reviewed as appropriate, including previously raised comments with regard to outputs and yielded benefits.</p> <p>IGARD noted that they had not had sight of the consent materials for the period 2015 -2018 and asked that these were provided with an analysis either in section 1 (Abstract) of the application or as a supporting document outlining how they met the duty of confidentiality.</p> <p>IGARD noted the application referred to previous “independent” approvals by IGARD’s predecessor the Data Access Advisory Group (DAAG) and asked that these were removed since DAAG as an independent review body became operational in September 2014 and the application was not reviewed since February 2013.</p> <p><b>Outcome:</b> IGARD welcomed the application which came for advice on the 2018 consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed.</p> <p><b>Advice on revised consent materials:</b></p> <ol style="list-style-type: none"> <li>1. To consider the use of the word ‘sex’ rather than ‘gender’, to be consistent with the type of data NHS Digital disseminates.</li> <li>2. To ensure the revised consent materials are sufficiently detailed and comprehensive to cover all the requirements of the research being undertaken or that may be undertaken in the future.</li> </ol>
---

	<ol style="list-style-type: none"> <li>3. To clarify the researcher's position on obtaining consent from under 16s and justify the chosen approach. IGARD suggested that, in reaching the view on current best practice, seeking the views of, inter alia, the NHS Digital Caldicott Guardian, the National Data Guardian, along with other relevant bodies.</li> <li>4. To explain why they are taking the parents' consent on all consent forms for those aged over 16 and to ensure that this reflects current best practice.</li> <li>5. To review paragraph 6 (vi) of the Patient Information Sheet in respect of the phrase of linking of HES 'with permission' and to be clear that the consent being taken covers this use of data and that separate future consent will <b>not</b> be sought.</li> <li>6. To remove reference to ONS and PHE collecting data.</li> <li>7. Within the Parents' Consent Form and the Patient Consent Form instead of using the term "anonymised", suggest using 'not directly identified'.</li> <li>8. Within the Patient Information Sheet to update the contradictory wording within the sentence starting "any personal data...".</li> </ol> <p><b>Advice on the application:</b></p> <ol style="list-style-type: none"> <li>1. To confirm whether children participants will be reconsented when they turn 16 and to ensure that the application reflects this.</li> <li>2. To ensure the appropriate ethical approvals are in place.</li> <li>3. 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 the latest within one month".</li> <li>4. To ensure that all previous comments raised when last reviewed by IGARD are fully addressed, including previously raised comments with regard to outputs and yielded benefits.</li> <li>5. To provide the consent materials for the period 2015 to 2018 with an analysis in the abstract or as a supporting document how they meet the duty of confidentiality.</li> <li>6. To remove reference to previous "independent" approvals by DAAG since independent review did not take place prior to September 2014.</li> </ol>
2.2	<p><u>University of Cambridge: MR480 - MRC Study of Cognitive Function and Ageing MR490 – Alpha Study (Liverpool) (Presenter: Rachel Farrand) NIC-147829-5K4QP</u></p> <p><b>Application:</b> This was an amendment application for identifiable Medical Research Information Service (MRIS) data. IGARD previously recommended for approval with conditions on the 10<sup>th</sup> January 2019 for the main cohort of the study only but did not include the sub-cohort of 47 participants who appear to have given consent and consequently do not appear to be covered by the s251 support. This application is to add the release of data for 47 consented participants who are excluded from the existing agreement. The studies are longitudinal population based epidemiological studies based in six areas of the UK and have recruited over 18,000 people and conducted in excess of 48,000 interviews over a period of more than 25 years. These studies have provided sound evidence generated by high quality population-based research to advance understanding of health and health changes with age.</p> <p><b>Discussion:</b> IGARD queried the reference within section 1 (Abstract) to The Higher Education Funding Council for England (HEFCE) and noted this had now been replaced by the Office for Students and asked that HEFCE was removed since it was no longer relevant.</p> <p>IGARD queried the reference to 'derived data' in section 5(b) (Processing Activities) and asked that an explanation was provided outlining the meaning of this; and to clarify any reference to 'onward sharing' concerned only derived data.</p>

	<p>IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: <i>“All data required by the Data Controller under this application is identifiable 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 the latest within one month”</i> and of the data being disseminated.</p> <p>IGARD noted within section 4 that the privacy notice did not meet the criteria set and asked that a special condition be inserted in section 6 (Special Conditions) that the applicant would provide a privacy notice that was compliant with the General Data Protection Regulation (GDPR) notice requirements and that it was published within one month of signing the Data Sharing Agreement (DSA).</p> <p>IGARD reviewed the consent materials for the cohort of 47 and noted the mild inadequacy regarding the details about and level of data flowing from NHS Digital to the research team (particularly, but not limited to, lack of reference to the cancer registry data and use of the word “flagged” without further explanation) and suggested the applicant rectify this via an updated privacy notice. IGARD asked that a special condition was inserted in section 6 (Special Conditions) stating that the applicant will make the revisions needed to meet the duty of confidentiality to the consented cohort when updating their privacy notice.</p> <p>IGARD noted that outputs were primarily research and advised that on return the application ought to provide further information about wider dissemination of outputs.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To remove reference to HEFCE from the abstract since it is not relevant.</li> <li>2. To provide an explanation within section 5(b) what ‘derived data’ is and to clarify any reference to ‘onward sharing’ concerned only derived data.</li> <li>3. To update section 4 with the standard wording “All data required by the Data Controller under this application is identifiable 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 the latest within one month”.</li> <li>4. To insert a special condition in section 6 that the applicant will provide a privacy notice that is compliant with the GDPR notice requirements and that it is published within one month of signing the DSA.</li> <li>5. To insert a special condition in section 6 that the applicant will make the revisions needed to meet the duty of confidentiality to the consented cohort when updating their privacy notice (see Advice below).</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD reviewed the consent materials for the cohort of 47 and noted the mild inadequacy regarding the details about and level of data flowing from NHS Digital to the research team (particularly, but not limited to, lack of reference to the cancer registry data and use of the word “flagged” without further explanation) and suggested the applicant rectify this via an updated privacy notice.</li> <li>2. IGARD noted that outputs were primarily research and advised that on return the application ought to provide further information about wider dissemination of outputs.</li> </ol>
2.3	<p><u>NHS Warrington CCG: DSfC - NHS Warrington CCG; RS, Comm &amp; IV (Presenter: James Humphries-Hart) NIC-47225-D8S4S</u></p>

	<p><b>Application:</b> This was an amendment application for pseudonymised Secondary Uses Service (SUS+), Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT) and Civil Registries Data (CRD). The data required is for Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care; Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; and to provide intelligence to support the commissioning of health services.</p> <p><b>Discussion:</b> IGARD queried the sentence within section 5(a) (Objective for Processing) <i>“Liaison Financial Services have no access to PDS systems or any other NHS system that can re-identify a patient from the NHS Number.”</i> and asked that this was removed from the application as it was not relevant.</p> <p>IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: <i>“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 the latest within one month”</i> and of the data being disseminated.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update the abstract and section 5(a) to remove the sentence <i>“Liaison Financial Services have no access to PDS systems...”</i>.</li> <li>2. To update section 4 with the standard wording <i>“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 the latest within one month”</i>.</li> </ol>
2.4	<p><u>Wolverhampton City Council: End of life data project (James Humphries-Hart) NIC-230538-B9J9Z</u></p> <p><b>Application:</b> This was a new application for Secondary Uses Service (SUS+) and identifiable Primary Care Mortality Data for a project that is aiming to provide a whole system overview of current end of life care and need within Wolverhampton; understand how and when people are identified as being at the end of their life; patients who have “expected” deaths without having been identified for end of life care; understanding what services people use at the end of their lives and how much is spent on these; discover where there are opportunities to redesign services to better meet the needs of Wolverhampton residents, ensure a good patient experience with financial sustainability, and reduce health inequalities.</p> <p>NHS Digital noted that section 3(b) (Additional Data Access Requested) needed amending to reflect that primary care mortality data is requested for the 2017 calendar year as outlined in section 5 (Purpose / Methods / Outputs) of the application.</p> <p>NHS Digital noted that the data minimisation column in section 3(b) currently held no information and needed populating and that it also needed to be made clear that the SUS data noted was pseudonymised.</p>

	<p><b>Discussion:</b> IGARD noted that supporting document 1, the data flow diagram was inconsistent with the application summary and asked that the diagram was updated.</p> <p>IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: <i>“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 the latest within one month”</i> and of the data being disseminated.</p> <p>IGARD noted the sentence in section 5(a) (Objective for Processing) <i>“The ICA works together on a number of workstreams and organisations within this collaboration...”</i> and asked that this was updated in terms easily accessible by a lay reader.</p> <p>IGARD noted the use of the term ‘pseudo-NHS number’ in section 5(b) (Processing Activities) and queried the meaning of this and asked that further investigation be undertaken to determine the use of this term and suggested it could be replaced with “pseudo id”.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend section 3(b) to reflect that primary care mortality data is requested for 2017 calendar year as reflected in section 5.</li> <li>2. To update section 3(b) to populate the data minimisation column and to state that the SUS data is pseudonymised 3(b).</li> <li>3. To update the data flow diagram to reflect the application summary.</li> <li>4. To update section 4 with the standard wording <i>“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 the latest within one month”</i>.</li> <li>5. To update the paragraph in section 5(a) <i>“The ICA works together on a number of workstreams and organisations...”</i> in terms easily accessible by a lay reader.</li> <li>6. To investigate the use of the term ‘pseudo-NHS number’ in section 5(b) and replace with “pseudo id”.</li> </ol>
2.5	<p><u>The Health Foundation: Funding pressures, phenotyping hospitals, penalising readmission and analysing factors associated with A&amp;E performance in England, patients with long-term conditions (Presenter: Louise Dunn) NIC-15411-C9Z9L</u></p> <p><b>Application:</b> This was an amendment and extension application for pseudonymised identifiable Hospital Episode Statistics (HES) and Civil Registrations data to complete ongoing work packages and to allow peer review of the work produced so far. The data series will be used for the following work packages: 1) The funding pressures facing health care in England for the next 15-20 years, and how service transformation can lead to greater sustainability 2) Phenotyping English Hospitals</p> <p><b>Discussion:</b> IGARD queried the reference to the study being “international” within section 1 (Abstract) and asked that a further explanation of this was included in section 5(a) (Objective for Processing) that outlined the nature of this and to clarify how this study fits into the wider international study. IGARD also asked for confirmation that no sharing of data will take place other than that outlined in the application.</p>

<p>IGARD noted that UK Cloud were listed as a data processor and queried if they were providing physical storage only and asked for further clarity on this and for the reference to them providing a cloud service to be removed from the application.</p> <p>IGARD noted within section 4 (Privacy Notice) that the privacy notice did not meet the criteria set and asked that a special condition be inserted in section 6 (Special Conditions) that the applicant will provide a privacy notice that is compliant with the General Data Protection Regulation (GDPR) notice requirements and that it is published within one month of signing the Data Sharing Agreement (DSA).</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: <i>"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 the latest within one month"</i> and of the data being disseminated.</p> <p>IGARD noted that the outputs listed in section 5(c) (Specific Outputs) did not refer to the most recent disseminations available and asked that this was updated to reflect recent work. IGARD also noted the information provided appeared to be out of date and referred to dates and actions that had already passed or had been completed and asked that this was updated to amend the tense where appropriate.</p> <p>IGARD queried the nature of the activities taking place at The Health Foundation and asked that section 5(b) (Objective for Processing) was updated to clarify this and to accurately describe where the researchers were undertaking the research, including the locations.</p> <p>IGARD queried the nature of the new processing being undertaken with the HES data and asked that section 5(b) was updated to reflect this; and to clarify if this data would be linked with any other data (for example NHS Digital, CPRD or other) to enable a comparison, and if there were linkages IGARD suggested to reflect this in the rest of the application.</p> <p>IGARD noted that a paragraph within section 5(a) that starts <i>"The largest amount of data is being requested for..."</i> was incomplete and asked that this was updated in terms easily accessible by a lay reader.</p> <p>IGARD noted the reference within section 1 when referencing legitimate interests that says "our" and asked that this was updated to correctly say "The Health Foundation".</p> <p><b>Outcome:</b> recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> <li>1. To insert an explanatory paragraph in section 5(a) outlining the nature of the 'international study' as referenced within the abstract and to confirm that no sharing of data will take place other than that outlined in this application; and to further explain how this study fits into the wider international study.</li> </ol> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To clarify if UK Cloud, listed as a data processor, are providing physical storage only and if so to remove the reference to them providing a cloud service.</li> <li>2. To update section 4 with the standard wording <i>"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 the latest within one month"</i>.</li> </ol>
--

	<ol style="list-style-type: none"> <li>3. To insert a special condition in section 6 that the applicant will provide a privacy notice that is compliant with the GDPR notice requirements and that it is published within one month of signing the DSA.</li> <li>4. To update the outputs in section 5(c) to reflect the most recent disseminations available and to amend the tense where appropriate.</li> <li>5. To update section 5(b) to clarify the nature of activities taking place at The Health Foundation and to accurately describe where the researchers are undertaking the research, including locations.</li> <li>6. To update section 5(b) to outline the nature of the new processing being undertaken with the HES data and to clarify if this data will be linked with any other data (for example NHS Digital, CPRD or other) to enable a comparison, and if there are linkages to reflect this in the rest of the application.</li> <li>7. To update and complete the paragraph within section 5(a) that starts “The largest amount of data is being requested for...” in terms easily accessible by a lay reader.</li> <li>8. To update section 1 (abstract) paragraph referencing legitimate interest from “our” to “The Health Foundation”.</li> </ol> <p>It was agreed the condition be approved OOC by the IGARD Chair</p>
2.6	<p><u>University of Aberdeen: MR76 - ORAL CONTRACEPTION STUDY (Presenter: Dave Cronin) NIC-147867-D8128</u></p> <p><b>Application:</b> This was a renewal and extension application for pseudonymised Medical Research Information Service (MRIS) for a study established in 1968 with the aim of determining the health effects of oral contraceptives and is one of the largest on-going studies of women’s health and oral contraception in the world. The aim of the study is to analyse the deaths of the study subjects, comparing the experience of users and non-users of oral contraceptives.</p> <p><b>Discussion:</b> IGARD welcomed this long running study but noted that no ethics approval was in place and that standards may have been different when the study commenced in 1968 and that data was pseudonymised. ACTION: IGARD asked, separate to this application, the Caldicott Guardian view with regard to historical applications of this nature and when REC approval should be sought and in addition the position with regard to data which would be pseudonymised</p> <p>IGARD noted that section 2(c) (Territory of Use) noted England and Wales as the territory of use and asked that this was amended to state”” United Kingdom”.</p> <p>IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: <i>“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 the latest within one month”</i> and of the data being disseminated.</p> <p>IGARD noted that the language used in section 5(a) (Objective for Processing) was historical and could be perceived as being quite dated and asked that a brief summary was added to the start of section 5(a) (Objective for Processing) stating that the way the study was outlined was based on language and attitudes reflective of the time the study was created and did not necessarily reflect the approach of the researchers today.</p> <p>IGARD noted the reference in section 1 (Abstract) to most of the study participants being “Caucasian” and queried whether that carried any significance to how the outputs were</p>

	<p>described in section 5 (Purpose / Methods / Outputs) in respect of referring to women generally, without any qualifier that the results are relevant to just one ethnic group; and asked that further consideration be given to this or that the reference to 'Caucasian' was removed if not relevant.</p> <p>IGARD queried the reference to 'non-users' in section 5(a) and how this cohort was formulated. NHS Digital noted that the applicant was comparing findings with national averages, however IGARD asked that the last paragraph was amended to reflect this information and clearly describe if this was by way of national averages or by another method.</p> <p>IGARD queried when NHS Digital had taken the decision that 'date of death' was not an identifier and NHS Digital confirmed this was prior to ONS data being made available via NHS Digital as Civil Registration Mortality Data and that data of death on its own was not an identifier. ACTION: IGARD asked separate to this application, that the formal information governance position on date of death not being an identifier be sought.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To amend the 'data processor area' in section 2(c) from England and Wales "" to United Kingdom "".</li> <li>2. 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 the latest within one month".</li> <li>3. To include a brief summary at the start of section 5(a) stating that the way the study is outlined is based on language and attitudes reflective of the time of the creation of the study and does not necessarily reflect the approach of the researchers today.</li> <li>4. To consider the reference to most study participants being "Caucasian" within the abstract and whether that carries any significance for how the outputs are described in section 5 (referring to women generally, without any qualifier that the results are relevant to just one ethnic group) or remove reference to "Caucasian" from section 1 if not relevant.</li> <li>5. To amend the last paragraph in section 5(a) that refers to a group of 'non-users' to outline how this cohort was formulated and to outline if this is by way of national averages or other method.</li> </ol>
2.7	<p><u>Kingston University London: Economic burden of HPV9-related diseases in UK (Presenter: Dave Cronin) NIC-200139-H2X2Y</u></p> <p><b>Application:</b> This was a new application for pseudonymised Hospital Episode Statistics (HES) to calculate hospitalisation rates associated with Human Papillomavirus (HPV) which is the most common sexually transmitted virus. The data will be used to calculate hospitalisation rates associated with HRGs. Namely the malignancies considered in the present application are cervical, vulvar, vaginal, penile, head and neck cancer. The study would estimate outpatient costs based on the information (e.g.: number of average visits) suggested by the extant literature and clinical experts. These costs would be associated to the appropriate tariff to calculate a measure of the average cost per patient.</p> <p><b>Discussion:</b> IGARD noted that there were inconsistencies in the application when describing the cohort and asked it was updated to ensure a consistent description of the cohort was detailed throughout the application and particularly within the data minimisation column in section 3(b) (Additional Data Access Requested).</p>

	<p>IGARD noted that historic phrasing was being used in section 4 (Privacy Notice) Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: <i>“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 the latest within one month”</i> and of the data being disseminated.</p> <p>IGARD noted the bold sentence in section 5(a) (Objective for Processing) <i>“There are no moral or ethical issues ... and no risk of potential harm at any stage of the processing activities.”</i> and suggested that this was amended to take a more neutral tone.</p> <p>IGARD suggested that on renewal further details of pathways of dissemination of the outputs and benefits be provided including examples of how they have promoted the outcomes of the research, since this will be of particular public interest.</p> <p><b>Outcome:</b> recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> <li>1. To update the application to ensure a consistent description of the cohort is detailed throughout the application and particularly within the data minimisation column in section 3(b).</li> <li>2. 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 the latest within one month”.</li> <li>3. To amend the bold statements in section 5(a) to take a more neutral tone.</li> </ol> <p>The following advice was given:</p> <ol style="list-style-type: none"> <li>1. IGARD suggested that on renewal further details of pathways of dissemination of the outputs and benefits be provided including examples of how they have promoted the outcomes of the research, since this will be of particular public interest.</li> </ol>
3	<p><b>AOB</b></p> <p>None</p>

### Independent Group Advising on Releases of Data (IGARD): Out of committee report 15/03/19

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)
<a href="#">N/A</a>						

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

- None