Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 14 March 2019

Members: Sarah Baalham, Maria Clark, Kirsty Irvine (Chair), Priscilla McGuire, Eve Sariyiannidou.

In attendance: Stuart Blake, Helen Buckles, Garry Coleman, Dave Cronin, Arjun Dhillon (item 2.10), Stephen Elgar, Rachel Farrand, Karen Myers, Kimberley Watson, Vicki Williams.

Apologies: Joanne Bailey, Anomika Bedi, Nicola Fear.

Observers: Dickie Langley (Item 2.9-2.10), Michael Robinson (Item 2.9), Geoffrey Schrecker

1	**Declaration of interests:** Maria Clark noted professional links to the University of Sheffield [NIC-68229-Y5J6V King's College London] but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 14th March 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record the meeting **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	3M United Kingdom PLC: Data extract to support the continued accuracy of 3M developed quality and performance indicators for commissioners and providers. (Presenter: Kimberley Watson) NIC-91972-S9W9T **Application:** This was an extension application for pseudonymised Hospital Episode Statistics (HES) data which will be used to anglicise the 3M APR-DRG and 3M CRG (grouper) solutions, specifically by supporting the development of crosswalk tables and algorithms between UK coding classifications (and other NHS Data Dictionary items) and their international equivalents. The application was been previously considered on the 17th January 2019 when IGARD had been unable to recommended pending: the applicant needs to understand and articulate the formal requirements that have to be met before it can use 'legitimate interest' as a legal basis and then to assess the legitimate interest in the context of the purpose of this application; since pseudo – anonymised data does not exist as a category, the applicant is to evaluate the data they use in connection to the GDPR requirements; to provide a GDPR compliant fair processing notice as the 'legitimate interest' legal basis is most appropriate where you use people's data in ways they would reasonably expect; to provide more detailed evidence of a project with (an) NHS organisation(s) which is proposed to start in the near future and define the purpose of this application in the context of that project; confirmation in the abstract or a supporting document that NHS Digital have assessed the Legitimate Interest Assessment and deemed it satisfactory; to amend section 5(a) to include the legitimate interest relied on and how it relates to the processing outlined within the application; to amend section 5(a) to provide further information on NHS clients referred to within the application; to amend section 5(c) to make the language more accessible to a lay

	reader with clearly defined timescales; to amend section 5(e) to clearly explain which aspect of the project is commercial. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made and in particular recognised the efforts made to address the legitimate interest assessment. IGARD noted within section 4 (Privacy Notice) that the privacy notice does 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). IGARD noted that the language used when describing the overall purpose and processing undertaken in section 5 (Purpose / Methods/ Outputs) was technical and may not be accessible to a lay reader and asked that this be amended either by way of a brief lay summary at the beginning of section 5, or efforts to explain technical terms (for example "crosswalk table") throughout. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement. IGARD noted that effort had been made to provide evidence of a project with NHS organisation(s) / clients and noted that they would expect to see significant progress when the application returns related to specific outputs produced and advised that they would wish to review this application again when it comes up for renewal rather than via Director / IAO approval. **Outcome:** recommendation to approve The following amendments were requested: 1. 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. 2. To amend section 5 outlining the overall purpose and processing undertaken in terms easily accessible by a lay reader. The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement. 2. IGARD advised that they would wish to review this application again when it next comes up for renewal. 3. IGARD noted that they would expect to see substantive details about the work undertaken for specific NHS clients and related outputs produced when the application returns.
2.2	<u>Clinical Practice Research Datalink (CPRD): PEARL Study (Prolonged Effects of Assisted reproductive technologies on the health of women and their children: a Record Linkage study for England) (CPRD-HFEA linkage project) (Presenter: Kimberley Watson) NIC-113025-X7Z3L</u> **Application:** This was a new application to carry out data linkage between Health Fertilisation and Embryology Authority (HFEA) infertility data and health data from the CPRD mother-baby track to assess the effect of assisted reproductive technologies (ART) on the health of women and their children after successful fertility treatment. This will support CPRD's aims in

	supporting vital public health research and to inform advances in patient safety in the delivery of patient care pathways. **Discussion:** IGARD queried the legal basis for the flow of confidential information from the Human Fertilisation and Embryology authority (HFEA) to NHS Digital for the cohort of participants that consented on the materials pre-2009 and asked for this to be clearly articulated. IGARD also queried the legal basis for the flow of data from HFEA to NHS Digital under GDPR and asked for this to be noted in the application. IGARD noted that section 5(a) (Objective for Processing) incorrectly stated in point 1 under the legal basis heading that there was a data flow from HFEA to the University of Oxford and asked that this be amended to reflect that there was no data flow, as accurately reflected in supporting document 1, the data flow diagram. IGARD noted that under the common law duty of confidentiality heading within section 3 (Datasets held / requested) it only listed section 251 as the legal basis and asked that this was updated to correctly list all the legal bases that are relevant to this application. IGARD noted that section 5 (Purpose / Methods / Outputs) did not clearly reference that other NHS Digital datasets were held by CPRD and that CPRD were creating a control group from CPRD data and asked that this was made explicitly clear along with clarification that routine data would be collected until the end of 2017. IGARD also asked that this information was referenced where relevant within section 3 and to cross-reference this with the narrative in section 5. IGARD noted that the first sentence within section 5(a) did not have the correct legal entity for the Department of Health and Social Care and asked this was amended. IGARD also noted the last part of the sentence *"This is the same arrangement for the data processor although it is CPRD who process the data but are not listed as data processors."* and asked that this was removed since it was not relevant. IGARD queried the different terms used throughout the application 'anonymised, 'de-identified', 'pseudonymised' and asked for justification for the use of the terms; or for the application to be amended to use 'pseudonymised' throughout and for consistency. IGARD noted that the application sometimes referred to CPRD as 'Clinical Practice Research Database' and asked that this was amended to consistently use the correct name of the' Clinical Practice Research **Datalink**' throughout. NHS Digital noted that the applicant had submitted their s251 renewal, however IGARD queried if s251 support was continuing for CPRD and suggested that NHS Digital should satisfy themselves of this. IGARD noted that section 5(c) (Specific Outputs) referred to a lay summary of the key findings being shared with charities and suggested that the applicant considers having lay involvement in the formulation of what will likely to be sensitive outcomes from the research. IGARD commended how detailed and well set-out the benefits were within section 5(d) (Benefits). **Outcome:** recommendation to approve subject to the following condition: 1. To articulate the legal basis for the flow of confidential information from HFEA to NHS Digital for the cohort of participants consented on the materials pre-2009. The following amendments were requested: 1. To provide the legal basis for the flow of data from HFEA to NHS Digital under GDPR.

	2. To update the common law duty of confidentiality heading within section 3 to correctly list all the legal bases relevant to this application. 3. To amend section 5 to make it explicitly clear that other NHS Digital datasets are held by CPRD, that CPRD are creating a control group from CPRD data, and to be clear that routine data will be collected until the end of 2017; and to also reference this information, where relevant, within section 3 cross-referencing to this narrative in section 5. 4. To amend the first sentence in section 5(a) to include legal entity of the data processor 'Department of Health and Social Care' and to remove the sentence "This is the same arrangement for the data processor…". 5. To amend section 5(a) point 1 (legal basis) to reflect that there is no data flow from HFEA to the University of Oxford. 6. To provide an explanation why there are different terms used throughout the application 'anonymised, 'de-identified', 'pseudonymised'; and to either provide a justification for the use of those terms or to amend the application to use 'pseudonymised' consistently throughout. 7. To amend the application to consistently use the correct name of the' Clinical Practice Research **Datalink**' throughout. The following advice was given: 1. IGARD suggested that NHS Digital should satisfy itself that s251 support is continuing for CRPD. 2. IGARD suggested that the applicant considers having lay involvement in the formulation and dissemination of the likely sensitive outcomes from the research. It was agreed the condition be approved OOC by IGARD Members.
2.3	<u>Queen Mary University of London: MR774 - The Evaluation of Breast Screening (Stuart Blake) (NIC-147747-KRTQ8</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) for the purpose of evaluating the breast cancer screening programme in terms of the reduction in breast cancer mortality associated with individual participation in the NHS Breast Screening Programme; the corresponding reduction in breast cancer mortality associated with individual participation in the NHS Breast Screening Programme; and the risk of overdiagnosis associated with participation in the programme. NHS Digital noted that additional supporting documentation with reference to s251 had been provided to IGARD for consideration **Discussion:** IGARD welcomed the application and noted the importance and significance of the study. IGARD noted that additional s251 information had been provided but noted there were gaps in the documentation provided for review. While accepting that s251 support continues in the absence of any documentary evidence to the contrary, IGARD noted that there was no evidence of the scope of the original s251 support that included the legal basis and the data covered, any special considerations and parameters of support. IGARD asked that this evidence of the original support was provided along with evidence that the support was continuing. IGARD queried the legal status of the Policy Research Unit (PRU) and asked for clarification of this; along with clarity that the PRU is a legal entity of the Queen Mary University of London and not the Department of Health and Social Care.

	IGARD noted reference to the use of 'over diagnosis' and suggested that the applicant reflect on the terminology since the study was just looking at mortality and suggested using a different phrase or removing it entirely from the application. IGARD noted the reference 'not-yet invited women' within section 5(c) and asked that this be removed as it was not relevant. **Outcome:** Recommendation to defer, pending: 1. To provide evidence of the scope of the original s251 support which provides the legal basis and the data covered, any special considerations, parameters of support and to provide evidence that the support is continuing. 2. Throughout section 5 to consider the use of the term 'overdiagnosis' and to consider using a different phrase or to remove. 3. To clarify the legal status of the Policy Research Unit (PRU) and to clarify that it is a legal entity of the Queen Mary University of London. 4. To remove reference to "not-yet-invited women" in section 5(c).
2.4	<u>CRAB Clinical Informatics: HES re-supply CRAB Clinical Informatics (Presenter: Stuart Blake) NIC-351722-W7D4N</u> **Application:** This was an amendment application relating to the applicant's ongoing pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC) and Critical Care (CC) monthly data release to cover an expanded customer base. The applicant and would like to provide benchmarking reports to NHS Trusts as well as to the established customer, the Care Quality Commission. CRAB Clinical Informatics Limited (C-Ci) is responsible for developing and marketing CRAB (Copeland Risk Adjusted Barometer), 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 help the Care Quality Commission (CQC) interpret mortality analysis (HSMR/SHMI) and understand safety in relation to avoidable harm, morbidity and areas for improvement. NHS Digital advised that an updated version of the Legitimate Interest Assessment (LIA) document had been provided by the applicant. **Discussion**: IGARD noted the update from NHS Digital in respect of the LIA and asked that NHS Digital's Customer Relationship Management system (CRM) was updated with the new document. IGARD noted that processing, outputs and benefits for the NHS Trusts and Care Quality Commission (CQC) outlined in the application were not clearly explained and asked that the whole application was reviewed to ensure this was clearly explained and that each organisations was delineated from one another. IGARD noted within section 4 (Privacy Notice) that the privacy notice does 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). IGARD queried the references to 'anonymised' data in section 5(a) (Objective for Processing) and asked for further clarity of the level of data provided when it refers to anonymised data. **Outcome:** recommendation to approve The following amendments were requested:

	1. To undertake a general review of the whole application to ensure that the narrative in respect of processing, outputs and benefits for the separate work streams for NHS Trusts and CQC are clearly explained and delineated from one another. 2. 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. 3. To provide further clarity in section 5(a) of the level of data provided when it refers to 'anonymised' data. 4. To update the CRM holder with the new Legitimate Interest Assessment (LIA) document.
2.5	<u>NHS Wakefield CCG: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand) NIC-204520-B1V2G</u> **Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) to both monitor and improve performance against the Cancer Waiting Time standards and to inform wider cancer pathway improvements. **Discussion:** IGARD queried why the CCG was accessing the data via NHS Digital, noting that in accordance with the Cancer Waiting Times (CWT) briefing note submitted to IGARD previously, the primary route for CCG's accessing this data is via the Data Services for Commissioners Regional Offices (DSCRO). IGARD asked for further clarity on this; and to also advise how this aligned with the advice provided in the CWT briefing note. IGARD queried the following non-standard text in section 5(b) (Processing Activities*) "As part of partnership working to improve Cancer Waiting Times performance, outputs may be shared with national / regional bodies including NHS England and NHS Improvement, Cancer Research UK, MacMillan, Yorkshire Cancer Research, Prostate Cancer UK, Breast Cancer Now, Bowel Cancer UK, Wakefield Metropolitan District Council, Leeds City Council, Bradford Metropolitan District Council, Kirklees Council, Calderdale Council, North Yorkshire County Council."* and asked for clarification as to why these recipients may be receiving data and at what level; or to remove the text from the application to conform with the standard CWT wording. IGARD noted the reference in the application to the Health and Care Partnership Analytics Team and asked for confirmation as to who they were and if members of the team were substantive employees of NHS Wakefield CCG. IGARD suggested that a consistent statement is used in the GDPR legal basis Article 6 about which legislation provides statutory functions for the CCG to carry out this type of work. IGARD noted that schedule 8 of the Data Protection Act 2018 was not referenced under the 'public task' section of the GDPR legal basis in the abstract. IGARD noted that references to Article 9(2)(h) GDPR should include the actual wording for this subsection. **Outcome:** recommendation to approve subject to the following conditions: 1. In light of fact in accordance with the Cancer Waiting Times briefing note, the primary route for CCGs to access data is via Data Services for Commissioners Regional Offices (DSCRO), to provide clarity why the CCG is accessing the data via this route and how that aligns with the advice provided in the CWT briefing note. 2. To remove the non-standard text from section 5(b) from the section that starts "As part of partnership working…" or provide clarification why these named recipients are getting data and at what level.

	3. To confirm who the Health and Care Partnership Analytics Team are and provide confirmation that they are substantive employees of Wakefield CCG. The following amendments were requested: 1. To amend references to Article 9(2)(h) of the GDPR to reflect the accurate wording. 2. To update the abstract sections on Article 6 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. The following advice was given: 1. To use consistent statement in the GDPR legal basis Article 6 about which legislation provides statutory functions for the CCG to carry out this type of work. It was agreed the condition be approved OOC by IGARD Members.
2.6	<u>NHS England Midlands and East: Cancer Alliance access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand) NIC-204517-W3N5Z</u> **Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) to both monitor and improve performance against the Cancer Waiting Time standards and to inform wider cancer pathway improvements. **Discussion:** IGARD noted that schedule 8 of the Data Protection Act 2018 was not referenced under the 'public task' section of the GDPR legal basis in the abstract and asked that it be included in section 1. **Outcome:** recommendation to approve The following amendment was requested: 1. To update the abstract sections on Article 6 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.
2.7	<u>Guy's and St Thomas' NHS Foundation Trust: Transforming Cancer Services Team for London access to National Cancer Waiting Times Monitoring Data Set (NCWTMDS) from the Cancer Wait Times (CWT) System (Presenter: Rachel Farrand) NIC-228903-Z0F4V</u> **Application:** This was a new application for pseudonymised National Cancer Waiting Times Monitoring Dataset (CWT) for the Transforming Cancer Service Team London, hosted by the applicant, to access data (previously supplied by NHS England) to provide London-wide support for improving cancer services and in terms of cancer waiting times, provide all the pan-London analysis across London, working with the Cancer Alliances to improve waiting times. **Discussion:** IGARD queried how the processing in this application aligned with the processing carried out by the same parties under various other CWT applications and asked for further clarity on this, since questions arose regarding excessive processing of the same data by the same organisations for similar purposes. IGARD also queried how the proposed processing met the necessity test in light of the data controller having access to CWT data via their role in the relevant Cancer Alliance (and other Cancer Alliances having access to the full geographical spread covered by the Transforming Cancer Services Team for London); and asked for further clarification for each section of the application how the processing, outputs and benefits differ from the activities carried out by this (and other) data controller(s) for various Cancer Alliances covering the same geographical area of the Transforming Cancer Services Team for London.

	IGARD noted references within the application to London and West Essex and asked for clarity of the remit of the application and whether this covered just London or London and West Essex, and that the application was amended accordingly. IGARD also asked that the data minimisation column in section 3(b) (Additional Data Access Requested) reflected the information provided in section 5 (Purpose / Methods / Outputs) and was amended to include West Essex. IGARD queried the references within section 5(a) (Objective for Processing) to the 'Healthy London Partnership' and asked for clarity on who they were, who was involved in the partnership, who was their substantive employer, what their relationship is with the Transforming Cancer Services Team and be clear who the legal entity was. IGARD noted that schedule 8 of the Data Protection Act 2018 was not referenced under the 'public task' section of the GDPR legal basis in the abstract. **Outcome:** Recommendation to defer, pending: 1. To clarify how the processing in this application aligns with the processing carried out by the same parties under various Cancer Waiting Times (CWT) applications; how the proposed processing meets the necessity test in light of the data controller having access to CWT data via their role in the relevant Cancer Alliance (and other Cancer Alliances having access to the full geographical spread covered by the Transforming Cancer Services Team for London); and to clarify for each section how the processing, outputs and benefits differ from the activities carried out by this (and other) data controller(s) for various Cancer Alliances covering the same geographical area of the Transforming Cancer Services Team for London. 2. To amend the data minimisation column within section 3(b) to include West Essex. 3. To clarify whether the remit of the application covers just London or London and West Essex and amend the application accordingly. 4. To provide further clarity on who the 'Healthy London Partnership' are and the relationship with the Transforming Cancer Services Team. 5. To update the abstract sections on Article 6 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.
2.8	<u>King's College London: Cognitive Behavioural Therapy for Dissociative (Non-Epileptic) Seizures: A Randomised Controlled Trial (CODES Study) (LREC LO/13/1595) (Presenter: Dave Cronin) NIC-68229-Y5J6V</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) data for a research study looking at patients who have dissociative (non-epileptic) seizures and whether cognitive behavioural therapy (CBT) may lead to a reduction in how often people have dissociative seizures. The CODES study is a large multi-site study being funded by the National Institute of Health Research Health Technology Assessment programme (NIHR HTA). The study was submitted in response to a call from the NIHR HTA in 2012 to create a study to examine a treatment for this condition and to examine the health care costs to individuals and the NHS. **Discussion:** IGARD queried why King's College London were considered sole data controllers for the study given the arrangements outlined in application and supporting documents. IGARD also noted that the information provided in the consent material referred to 'we' rather than a specific organisation which implied there are more than one organisation involved with the decision making; taking this into consideration IGARD asked that South London and Maudsley NHS Foundation were also added as a joint data controller.

	IGARD noted the study website link that was referenced within section 1(a) (Abstract) and asked that this was also referenced within section 5(c) (Specific Outputs) since the website was publicly visible and contained a lot of information which may be of interest to the public or study participants. **Outcome:** recommendation to approve subject to the following condition: 1. To add South London and Maudsley NHS Foundation Trust as joint data controllers and to amend the application throughout to reflect this. The following amendment was requested: 1. To replicate the reference to the study website noted within the abstract in section 5(c). It was agreed the condition be approved OOC by IGARD Members.
2.9	<u>Use of cloud computing services for NHS data – Briefing Paper (Presenters: Stephen Elgar / Helen Buckles)</u> The briefing paper was to inform IGARD of arrangements for approved use of cloud data storage services for a Digital Access Request Service (DARS) application. As defined by the National Institute of Standards and Technology: "Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g. networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction." The briefing noted that all public sector and many private organisations are considering use of cloud data storage because of the lower costs and greater flexibility that this type of service offers. A care sector-wide policy has recently been developed and usage is increasing for the public sector, by NHS and Local Authorities and by Universities. Noting that this briefing is still a "work-in-progress", IGARD welcomed the draft briefing paper and offered to support drafting an NHS Digital Standard on Cloud Storage.
2.10	<u>The Brain Tumour Charity (TBTC): BRIAN (Brain Tumour Information and Analysis Network) is an online information system that will enable patients to make better-informed decisions about their treatment and accelerate research to find a cure. (Presenters: Garry Coleman / Helen Buckles) NIC-158754-R5T3V</u> **Application:** This was an amendment application for pseudonymised Hospital Episode Statistics (HES) data, Diagnostic Imaging Dataset (DIDs) and Civil Registrations data**.** The request was also to add Microsoft Azure Cloud storage as a data processor, processing and storage location. TBTC has a strategy to double survival and halve the harm that brain tumours have on quality of life, one of the ways TBTC strives to achieve this strategy is by funding research and the aim is to establish a research database (BRIAN) which can be used to facilitate research projects from third parties with suitable permissions and to enable cohort data to be included and selected from a data dictionary. BRIAN will also allow those patients who have consented to access their own identifiable medical records and read them in plain text. NHS Digital noted that the information provided in the 'identifiability' column within section 3(a) (Data Access Already Given) was incorrect and would need amending to correctly note that the data was pseudonymised not identifying. NHS Digital noted that the application referred to 'sub-licencing' and confirmed that this was a future plan and was not part of this application.

	NHS Digital clarified that patients will be reconsented when they reach the age of 16. **Discussion:** IGARD noted and supported the amendment outlined by NHS Digital in relation to section 3(a) being updated to correctly reference pseudonymised data. IGARD noted the clarification from NHS Digital on 'sub-licencing' and asked that is was made clear within the application that was a future plan and not part of the application. IGARD noted the update from NHS Digital that patients would be reconsented when they reached the age of 16 and asked that paragraph 1 in section 5(b) (Processing Activities) was updated to confirm this. 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: "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" and of the data being disseminated. IGARD queried the reference in section 5(a) (Objective for Processing) *"BRIAN will be linked with relevant ODS Standard Repository Data (anonymous)…"* and asked for clarity as to why the ODS Standard Repository Data was deemed anonymous. IGARD queried the reference to 'medical record' in section 5 (Purpose / Methods / Outputs) and suggested revising the use of this term as it was not clear exactly what this meant. IGARD also suggested that the applicant should carefully consider the use of the term 'medical records' within patient facing materials due to the particular meaning ascribed to this word within the NHS, as it may not be what research participants are actually able to access on BRIAN. IGARD queried information noted in the consent material that implied that access to BRIAN and the valuable resources was only granted if patients consented to the study and asked for clarification on this. IGARD suggested consideration be given to making these resources available to patients on a more generic basis, and not contingent on consent. IGARD suggested that the applicant consider whether it would be best practice to also seek consent from age appropriate competent children. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the information within the 'identifiability' column in section 3(a) to correctly note that the data is pseudonymised. 2. To be clear within the application that the "sub-licensing" referred to is a future plan and not part of this application. 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". 4. To provide clarity as to why the 'ODS Standard Repository Data' as referenced in section 5(a) is deemed 'anonymous'. 5. To provide clarity within paragraph 1 section 5(b) that patients will be reconsented when they reach the age of 16. 6. To consider revising the use of the term 'medical record' within section 5 (see also point of advice below).

	7. To clarify whether consent to the study is required before being granted access to the valuable resources available on BRIAN, and if so to consider making these resources available to patients on a more generic basis, not contingent on consent. The following advice was given: 1. IGARD suggested that the applicant should carefully consider the use of the term 'medical records' within patient facing materials due to the particular meaning ascribed to this word within the NHS as it may not be what research participants are actually able to access on BRIAN. 2. IGARD suggested that the applicant consider whether it would be best practice to also seek consent from age appropriate competent children.
3	**AOB** None

Independent Group Advising on Releases of Data (IGARD): Out of committee report 08/03/19

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)
NIC-15741-J6Y4L	Queen Mary University of London	14/02/19	1. To add Public Health England as a joint Data Controller and make any necessary amendments to the application to reflect this.	IGARD Chair	IGARD Chair	N/A

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

- None