<p style="text-align:center">**Independent Group Advising on the Release of Data (IGARD)**</p>

<p style="text-align:center">**Minutes of meeting held 17 October 2019**</p>

In attendance (IGARD Members): Anomika Bedi, Maria Clark, Kirsty Irvine (Chair), Geoffrey Schrecker, Maurice Smith.

In attendance (NHS Digital): Garry Coleman (GC) (Items 2.1 – 2.2), Louise Dunn, Dickie Langley, Karen Myers.

Not in attendance (IGARD Members): Sarah Baalham, Nicola Fear, Eve Sariyiannidou.

Observers: Jon Coolican (Items 2.1-2.2), Shona Gallagher (Items 2.3 onwards), Stuart Gunson (Items 2.1-2.2), Ross Jenkins (Item 2.3 onwards)

1	**Declaration of interests:** Anomika Bedi noted a professional link to Medicines and Healthcare Products Regulatory Agency (NIC-15625-T8K6L) and would not be part of the discussion. It was agreed that Anomika would not remain in the room for the discussion of that application. Maria Clark noted professional links to the Royal College of Surgeons (NIC-136916-B7D5C), 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 10th October 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	<u>Clinical Registries, Databases and Audits – Briefing Paper (Presenter: Dickie Langley)</u> The briefing paper was to inform IGARD about the new Clinical Registries, Databases and Audits product. In line with the Data Services for Commissioners Directions, NHS England requires defined clinical data extracts from specified Clinical Databases, Registries and Audits to be able to fulfil their statutory functions as a commissioner of NHS Services, as determined by the Health and Social Care Act 2012. The briefing was an 'overarching briefing' which intends to cover all relevant information to the inclusion of any clinical database or audit in the NHS England and NHS Digital Data Sharing Agreement (DSA) as all the material details in terms of legal basis for the purposes for and processing of the data flows is the same for all Clinical Database, Registry and Audit extracts. IGARD welcomed the briefing paper and looked forward to receiving the updated paper in 1 month (to be presented to IGARD on the 7th November 2019). IGARD provided the following comments: 1. In respect of the National Hip Fracture Database (NHFD) data set, to address the role of the Healthcare Quality Improvement Partnership (HQIP) i.e. whether it is a joint Data Controller with NHS England, a Data Controller or a Data Processor. 2. To make it clear that the briefing paper relates to a product currently containing just four data sets. 3. To outline that as each new data set is added to the product the briefing paper will be amended as necessary (including by way of additional appendices).

4. To address the legal requirements in respect of data minimisation, to give further consideration as to how each applicant's request for the product will address which data sets can be contained in the data delivery (as not all applicants will have a demonstrable need for each data set in the product, particularly as the product grows in size).

5. To make it clear that this briefing paper is designed for commissioning and to prominently outline what it does **not** cover at the forefront of the paper. In particular to note that at this stage, the paper is focused on commissioning by NHS England for specialised services. The briefing paper will need to be enhanced to specifically address commissioning by the CCGs.

6. In respect of the legal bases for the data received by NHS Digital, to rework section 9 so that the various different legal bases are covered (for example: Directions, different sections of the Health and Social Care Act).

7. In respect of each data set to consider how to notify applicants whether opt outs have been applied before data collection or during data transfer.

8. To address the issue of confidentiality in the note and highlight that, depending on the data set, any duty of confidence may be addressed by Direction, s251 support, consent or some other means.

9. To remove reference to the Information Commissioner's Office (ICO) Code of Practice and/or amend in line with a form of wording agreed with NHS Digital Information Governance.

10. To ensure careful use of the word "anonymised" and check in each case that "pseudonymised" is not more accurate.

11. To ensure the Data Protection Impact Assessment (DPIA) is finalised and is congruent with the briefing note (for example, the legal gateway for NHS Digital to receive the data should be harmonised between the two documents).

12. Remove the reference to "20 years" in paragraph 13.

2.2	NHS England (Quarry House): NHS England - DSfC - NCDR amendment 2019 (Presenter: Dickie Langley) NIC-139035-X4B7K

Application: This was an amendment application to NHS England's National Commissioning Data Repository agreement to include Clinical Registry data; and a renewal application for pseudonymised Children and Young People's Health Services (CYPHS), Secondary Use Service (SUS) for Commissioners, Local Provider Flows, Community Services Data Set (CSDS), Mental Health Learning Disability Data Set (MHLDDS), Diagnostic Imaging Data Set (DIDs), Improving Access to Psychological Therapies (IAPT), Mental Health Minimum Data Set (MHMDS), Maternity Services Data Set (MSDS), Civil Registration, Mental Health Services Data Set (MHSDS), National Cancer Waiting Times (CWT), National Diabetes Audit (NDA), Community Services Data Set (CSDS), Assuring Transformation (AT), Patient Reported Outcome Measures (PROMs).

NHS England requires access to data collected within Clinical Registries, Databases and Audits. Part of NHS England's responsibility is to oversee the budget, planning, delivery and day-to-day operation of the commissioning side of the NHS in England as set out in the Health and Social Care Act 2012.

NHS Digital advised IGARD that following submission of the application, a number of amendments had been identified and the application would need updating to reflect these, which included; amending section 5(a) (Objective for Processing) to make it clear that the identifiable data was only identifiable when it was with NHS Digital, **not** after dissemination by NHS Digital; to update section 5(b) (Processing Activities) to add Clinical Registry Data to the list of data sets; to remove the final paragraph from section 5(c) (Specific Outputs Expected)

and to insert a paragraph setting out clearly how the new Registries are added to the new registry product.

Discussion: IGARD noted and supported the updates from NHS Digital on the various amendments / updates to the application that included amending section 5(a) to make it clear that identifiable data was only identifiable when it is with NHS Digital and to update section 5(b) to add Clinical Registry Data to the list of data sets. IGARD asked that in relation to the last update 'to remove the final paragraph from section 5(c) and to insert a paragraph setting out clearly how the new Registries are added to the new registry product', that it was also made clear that such change control process would have IGARD input and agreement.

IGARD queried the information in section 5(a) that outlined information on *"savings"* and "*patient benefit*" and suggested that this was removed and replaced with the objectives for the Improving Access to Psychological Therapies (IAPT) data. IGARD also noted the reference to *"PBR currency"* in section 5(a) and asked that this was removed.

IGARD noted the sentence in section 5(b) that stated *"All access to data (by data controllers and data processors) is managed under Role-Based Access Controls."* and asked that this was updated to *"…Role **and Task Based** Access Controls…";* and that this full sentence was replicated as a special condition in section 6 (Special Conditions).

IGARD queried the information provided in the data minimisation column in section 3(b) (Additional Data Access Requested) that stated *"National data covering England"* and asked that this was updated to correctly specify the Registries available and used within this application; and that this information was also replicated in section 5(c).

IGARD noted the information in section 5 (Purpose / Methods / Outputs) was at times difficult to understand and asked that to aid readability and comprehension, the new text that related to the Clinical Registry Data was reviewed, to ensure the language and style fitted with the rest of section 5 and in language suitable for a lay reader.

IGARD advised that when the application returned for renewal, IGARD would expect to see, as far as possible, further updated information with regard to the stated benefits, projections and objectives and that if the refreshed data was not available, to ensure all statements about projected or anticipated benefits were realistic and achievable with the data requested.

Outcome Summary: The application was recommended for approval for a period of 2 months and should be presented again to IGARD on the 12th December; in conjunction with the updated Clinical Registries Briefing Paper (which should be presented to IGARD in 1 month on the 14th November 2019).

The following amendments were requested:

1. To amend section 5(a) to make it clear that the identifiable data is only identifiable when it is with NHS Digital, **not** after dissemination (by NHS Digital).
2. To update section 5(b) to add Clinical Registry Data to the list of data sets.
3. To remove the final paragraph from section 5(c) and to insert a paragraph setting out clearly how the new Registries are added to the new registry product and to make clear that such change control process will have IGARD input and agreement.
4. To remove from section 5(a) the information on the *"savings" and "patient benefit"* and replace with the objectives for IAPT data.
5. To remove from section 5(a) the sentence that refers to PBR currency.
6. To update the reference in section 5 to *"…Role **and Task** Based Access Controls…"* and to replicate this full sentence as a special condition in section 6.

	7. To update the data minimisation column in section 3(b) to correctly specify the Registries available and used within this application; and to replicate this in section 5(c). 8. To review the new text that relates to the Clinical Registry Data and ensure the language and style fits with the rest of section 5. The following advice was given: 1. IGARD advised when the application returns for renewal, IGARD would expect to see, as far as possible, further updated information with regard to the stated benefits, projections and objectives (and if refreshed data is not available, to ensure all statements about projected or anticipated benefits are realistic and achievable with the data requested).
2.3	<u>University College London: Evaluating the Family Nurse Partnership in England (Presenter: Dickie Langley) NIC-136916-B7D5C</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), Civil Registrations and Medical Research Information Service (MRIS) data for a longitudinal research study aiming to evaluate the real-world implementation of the Family Nurse Partnership (FNP) in England. FNP is an intensive early home visiting programme for first time young mothers, delivered by trained nurses aiming to improve maternal and child outcomes by providing support throughout pregnancy and until the child's second birthday. The study aims to evaluate the real-world implementation of FNP in England with findings from the study helping policy makers decide whether FNP should be offered to families in their local setting. The application was been previously considered on the 25th July 2019 when IGARD had deferred pending: to clarify whether the study is part of an EU funded project and, if that is the case, section 5 should be revised to reflect recent IGARD advice on the criteria for assessing applications which are EU funded; to clarify how the FNP cohort data was created and what the legal gateway is for the applicant to process that data; to provide further details of the collaborators listed in the protocol and confirm their role, how they fit with the study and why they are not considered joint Data Controllers and / or Data Processors; to provide written evidence that the HRA CAG conditions of support have been satisfied; to clarify how the data in section 3(a) has been populated including the data minimisation efforts undertaken, for example that this is a subset of data held under another Data Sharing Agreement and that this narrative also be included within section 5(a); to complete the data minimisation column in table 3(b); to explain how the benefits of the research will be realised when the cohort data disseminated under this application only appears to relate to the Mother and not the infant/child. IGARD suggested that NHS Digital discuss with the applicant whether the data set requested is the best fit for the proposed processing; to provide a clear narrative why the large control group (975,000) is necessary rather than a significantly smaller stratified sample for comparison; to consider the nature of the cohort with regards to the dissemination and content of the transparency materials; IGARD suggested that the applicant give consideration to additional pathways of dissemination of the outputs to ensure the impact and reach of the outputs is maximised. **Application:** IGARD noted that the application had been updated to reflect all of the comments previously made. IGARD queried the reference within supporting document 2, the Protocol that the Study Steering Committee Chair was from the University of Oxford, and asked that section 5(a)

(Objective for Processing) was updated to add them to the organisations listed that were involved with the study (but who were not joint Data Controllers).

IGARD noted the references in section 5(a) to babies being "delivered" and suggested that consideration was given to instead use the term *"babies born"* in line with current preferred usage.

IGARD queried the special condition in section 6 (Special Conditions) that stated *"if the CAG approval is not extended beyond the first or any subsequent annual review then this agreement will become **null and void"*** and suggested that this was updated to remove the term *"null and void"* and replaced with *"terminated"*.

Outcome Summary: recommendation to approve

The following amendments were requested:

1. To update section 5(a) to include the University of Oxford to the list of organisations involved in the study (but who are not joint Data Controllers).
2. To consider the language used in section 5(a), for example replacing the term *"delivered"* with *"babies born"*.
3. To update the special condition in section 6 to remove the term "null and void" and replace with "terminated".

| 2.4 | University College London: The role of IAPT in the prevention of dementia and the amelioration of its impact on service use and co-morbidities (the MODIFY project) (Presenter: Dickie Langley) NIC-157211-T8B2M |

Application: This was a new application for pseudonymised Improving Access to Psychological Therapy (IAPT), Hospital Episode Statistics (HES), Mental Health Services Data Set (MHSDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Minimum Data Set (MHMDS) and Civil Registrations data.

The project aims to enhance understanding of dementia prevention in the UK by examining the role of psychological therapies offered within the England-wide Improving Access to Psychological Therapies (IAPT) services in dementia prevention; and to try and determine whether receiving successful treatment for anxiety and depression is associated with reduced risk of developing dementia.

NHS Digital advised IGARD that following submission of the application, a number of amendments had been identified and the application would need updating to reflect these, which included; removing the reference to *"and all data processors accessing the system"* from section 5(b) (Processing Activities); removing the reference to "*See Special Conditions"* from section 5(c) (Specific Outputs Expected); removing the reference to *"ONS"* data from the table in section 7 (Approval Considerations); to update the data minimisation column in section 3(b) to remove reference to *"See Additional Production Detail"* and replace with either further details of the data minimisation OR to provide a reference to section 5 that details this; and to update section 1 (Abstract) to include details of the control over students on 'honorary contracts' (or suitable alternate description).

Discussion: IGARD noted and supported the updates from NHS Digital on the various amendments / updates to the application that included removing the reference *"and all data processors accessing the system"* from section 5(b); removing the reference in section 5(c) to "*See Special Conditions";* removing reference to *"ONS"* in section 7; removing reference to *"See Additional Production Detail"* in section 3(b) and replacing with either further details of the data minimisation OR to provide a reference to section 5 that detailed this; and to update section 1 to include details of the control's over students on 'honorary contracts'.

IGARD noted information provided in the application that clarified that the cohort age group was 30-45, however queried what the scientific justification was for processing the data for this age group and asked that supporting document 5, the Protocol was revised to reflect this information; or that suitable Protocol-standard wording was provided clearly setting this out.

IGARD queried if the "honorary contracts" with the students were fit for purpose, for example noting that the students involved were University College London students and it was not clear who the parties to the contract would be and if the contract contained the usual controls and sanctions around misuse of data. It was suggested that a 'code of conduct' or similar might be more appropriate. NHS Digital agreed with IGARD's concerns and it was suggested that revised material be provided to NHS Digital and they would review and provide confirmation to IGARD when they were satisfied with the revised materials.

IGARD endorsed NHS Digital's review that the applicant's privacy notice does meet NHS Digital's fair processing criteria for privacy notices and further noted that this should also be updated to make reference to articles of the General Data Protection Regulation (cf the Data Protection Act) and to make it explicitly clear that they were not able to identify any of the data subjects directly.

Outcome Summary: recommendation to approve subject to the following conditions:

1. To revise the Protocol or to provide suitable Protocol-standard wording to IGARD that clearly sets out the scientific justification for processing the data for the cohort age group from 30 to 45 years old.
2. Confirmation from NHS Digital that they are satisfied that the revised contracts with the students are fit for the proposed purpose (for example using a Code of Conduct agreement rather than an "Honorary Contract"), and for such agreement to cover off appropriate protections such as sanctions for misuse of data, and that the parties involved have been clearly identified.

The following amendments were requested:

1. To update section 5(b) to remove the sentence *"and all data processors accessing the system"* as it is not relevant.
2. To remove from section 5(c) the reference to *"See Special Conditions".*
3. To remove the reference to *"ONS"* in section 7.
4. To update the data minimisation column in section 3(b) to remove reference to *"See Additional Production Detail"* and replace with either further details of the data minimisation OR a reference to section 5 that details this.
5. To update section 1 to include details of the control over students on 'honorary contracts' (or suitable alternate description).

The following advice was given:

1. IGARD suggested that the applicant's fair processing notice should be updated to make reference to articles of the GDPR (cf the Data Protection Act) and to make it explicitly clear that they are not able to identify any of the data subjects directly.

It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.

2.5	Medicines and Healthcare Products Regulatory Agency (MHRA): Clinical Practice Research Datalink (CPRD) Routine Linkages Application (Presenter: Louise Dunn) NIC-15625-T8K6L
	Application: This was an extension application; renewal for pseudonymised Hospital Episode Statistics (HES), Patient Reported Outcome Measures (PROMs), Mental Health Services Data Set (MHSDS), Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Civil Registration, Diagnostic Imaging Data Set (DIDS); and an

amendment to specifically include the flow of the Asthma and Chronic Obstructive Pulmonary Disease (COPD) data using the same agreed processes already approved for other datasets within this agreement.

The purpose is to support vital public health research and to inform advances in patient safety in the delivery of patient care pathways. These depend on access to accurate, real-time representative patient data to produce reliable evidence based clinical and drug safety guidance.

NHS Digital advised IGARD that there was information in section 6 (Special Conditions) that referred to *"ONS"* data; and advised that this would need removing as it was not relevant.

Discussion: IGARD noted the update from NHS Digital advising that the reference to ONS would need removing and supported the amendment to section 6.

IGARD noted the information throughout the application confirming that NHS Digital had permitted CPRD to share data with third parties via a sub-license(s), and asked that a new "Sub-licensing" section was added to the application to either draw all the information and statements together; or to add additional information / references identifying where the supporting information could be found. IGARD also asked that all of the requirements of NHS Digital's Sub-licensing Standard (Standard 10) were addressed.

IGARD noted point 9 of the Sub-licensing Standard that stated *"The Applicant should take responsibility for the actions and omissions of all sub licencees and breach of a sub licence should automatically be regarded as breach of the Data Sharing Framework Contract."* and asked that this was added as a special condition in section 6 (Special Conditions).

Outcome Summary: recommendation to approve subject to the following condition(s)

1. To insert a new "Sub-licencing" section in the application to draw together all the statements (or to include additional information or refer to where supporting information can be found) to address all of the requirements of NHS Digital's Sub-licencing Standard.

The following amendments were requested:

1) To include the response to point 9 of the Sub-licence Standard as a special condition in section 6.

2) To update the application to remove reference to *"ONS"* data.

It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.

| 2.6 | NHS Buckinghamshire CCG: DSfC - NHS Buckinghamshire CCG - COMM, RS & IV (Presenter: Louise Dunn) NIC-186888-X2K6T |

Application: This was a renewal 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), Civil Registries Data (CRD), National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs); and an amendment to add Graphnet Healthcare Ltd for the purpose of Risk Stratification and to add Microsoft UK as a Data Processor.

The purpose is for the purpose of Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do, 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; and to provide intelligence to support the commissioning of health services.

Discussion: IGARD had a lengthy discussion in relation to Risk Stratification and it was agreed that to support this going forward, IGARD and NHS Digital would review the Risk Stratification Precedent. IGARD also confirmed that they would speak with the Caldicott Guardian regarding the difficulty of applying the national data opt-out, in-line with operational guidance, where the Data Processor is receiving identifiable data which is used for both direct care and purposes other than direct care.

IGARD noted that the yielded benefits in section 5(d) (iii) had not been completed and asked that this was updated to reflect this information.

IGARD noted the reference in section 5(c) that Graphnet Healthcare Ltd would be working in partnership with the US organisation John Hopkins ACG, and asked that a special condition was added to section 6 (Special Conditions) confirming that no data would be shared with John Hopkins ACG.

IGARD queried how the identifiable data would be flowed to the CCG's and asked that a special condition was added to section 6 stating that the identifiable data would not flow to the CCG's via Graphnet Healthcare Ltd.

IGARD queried what pseudonymised and identifiable data flowed between the Data Processors, GP's and the CCG's as outlined in the application, and asked that further clarification was provided outlining this.

IGARD noted the information provided in section 5(b) (Processing Activities) on *"segregation"* and asked that this was amended to clarify that the data would be segregated from that for the purpose of direct care.

IGARD noted the statement provided in section 5(b) that stated *"Microsoft UK supply Cloud Services for Graphnet Healthcare Ltd and are therefore listed as a data processor. They supply support to the system, but do not access data. Therefore, any access to the data held under this agreement would be considered a breach of the agreement. This includes granting of access to the database[s] containing the data."* and asked that this was amended to make it explicitly clear that Microsoft UK would store but not otherwise process the data.

IGARD suggested that NHS Digital encourage the applicant to consider the processing activities in light of the General Data Protection Regulation (GDPR) requirements, including (but not limited to) ensuring that their fair processing notice accurately and explicitly reflects the profiling taking place and, if relevant, any automated decision making that will take place.

ACTION: NHS Digital / IGARD to review the Risk Stratification Precedent.

ACTION: IGARD to discuss with the Caldicott Guardian the difficulty of applying the national data opt-out, in-line with operational guidance, where the Data Processor is receiving identifiable data which is used for both direct care and purposes other than direct care.

Outcome Summary: recommendation to approve

The following amendments were requested:

1. To update the yielded benefits section of the application.
2. To update section 6 to include a special condition that no data will be shared with John Hopkins ACG.
3. To update section 6 to include a special condition that the identifiable data does not flow to the CCG's via Graphnet Healthcare Ltd.

	4. To set out further clarification of the flows of pseudonymised and identifiable data between the Data Processors, GP's and CCG's. 5. To amend the *"Segregation"* section in 5(b) to clarify that the data will be segregated from that for the purpose of direct care. 6. To amend section 5(b) to make explicitly clear that Microsoft UK will store but not otherwise process the data. The following advice was given: 1. IGARD suggested that NHS Digital encourage the applicant to consider the processing activities in light of GDPR requirements, including (but not limited to) ensuring that their fair processing notice accurately and explicitly reflects the profiling taking place and, if relevant, any automated decision making that will take place.
3	<u>Returning Application - NIC-54736-M5M1L NHS Fareham and Gosport CCG</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. IGARD welcomed the application as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight & Assurance Report which will be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.
4	**AOB:** There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 11/10/19

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-190086-F5Z7B	St George's, University of London	26/09/19	1. To provide a written justification why CRY is not considered a joint Data Controller, in light of the protocol provided which describes CRY as the Data Custodian and shows one of the two investigators is a substantive employee of CRY, or to include CRY as a joint Data Controller.	IGARD Members	Quorum of IGARD Members	N/A
NIC-148239-M8RTP	University of Oxford	25/04/2019	1. To update the study page on the NPEU website	IGARD Chair	IGARD Chair	The application was designated as one to return to IGARD upon renewal

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

- None