Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 6th February 2020

In attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Maria Clark, Nicola Fear, Kirsty Irvine (Chair).

In attendance (NHS Digital): Stuart Blake, Garry Coleman (Item 2.4), Louise Dunn, Karen Myers, Kimberley Watson (Item 2.4), Vicki Williams.

Not in attendance (IGARD Members): Geoffrey Schrecker, Maurice Smith.

Observers (New IGARD Members): Paul Affleck, Imran Khan.

1	**Declaration of interests:** Anomika Bedi previously noted a potential professional link to Medicines and Healthcare Products Regulatory Agency (NIC-15625-T8K6L), however advised that this had now lapsed and would therefore be able to remain in the room and be part of the discussion for this application. **Review of previous minutes and actions:** The outcomes of the 30th January 2020 IGARD meeting were reviewed and were agreed as an accurate record of that aspect of the meeting. The minutes of the 30th January 2020 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meetings. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	<u>IQVIA Ltd: NIC-373563 - IQVIA Ltd & IQVIA Technology Services Ltd (Presenter: Louise Dunn) NIC-373563-N8Z9J</u> **Application:** This was a renewal application for pseudonymised Hospital Episode Statistics (HES) and Emergency Care Data Set (ECDS); and an amendment to add Civil Registrations mortality data; to add a coding audit service to service 2 and to add clinical analyses to service 2. The purpose is to perform two types of services: 1) Data Visualisation and Benchmarking (the "Service 1" services). This is a suite of software tools into which the relevant Data is loaded, which enables users to view metrics using tables, maps and charts; 2) Advanced Statistical Analysis (the “Service 2” services) is bespoke analysis for external organisations on a project by project basis. **Discussion:** IGARD queried the type of Civil Registrations data that was being requested and were advised by NHS Digital that this was mortality data only; IGARD asked that the application was updated to accurately reflect this. In addition they noted and endorsed NHS Digital’s review that the applicant did **not** meet NHS Digital’s Standard for privacy notices; and suggested that the applicant may wish to update their Privacy Notice to ensure it reflected the Civil Registration data requested under this application. IGARD queried what NHS Digital’s view was on the ‘date of death’ field being identifiable; and were advised by NHS Digital that this topic had been carefully analysed and that it was NHS Digital Policy that this was treated as ‘non-identifiable’.

	IGARD noted the reference in section 5(a) (Objective for Processing) to holding *"back data for 5 years"* and were advised by NHS Digital that at any given time the applicant wanted a full 5-years back data **plus** any data from the current year; IGARD asked that the application was updated throughout to reflect this information. IGARD queried the statement in section 5(e) (Is the purpose of this application in anyway commercial?) *"The commercial element while present and relevant is secondary to the primary purpose of processing for research purposes."* and asked that this was rephrased in terms that, whilst there was a commercial benefit, that this must be proportionately balanced against benefits to the health and social care system, as outlined in NHS Digital's published 5e Commercial Purpose Standard. IGARD queried the two new projects briefly referred to in section 5(a), specifically *"coding audit"* (Amendment iv) and *"understanding therapies"* (Amendment v); and asked that further information / clarity of these projects were provided in both section 1 and section 5(a). IGARD also asked that section 5 (Purpose / Methods / Outputs) was updated throughout to reflect the two new projects. IGARD noted the outputs outlined in section 5(c) (Specific Outputs Expected) and asked that they were updated further to accurately reflect the new services and amendments added to the revised application. IGARD queried the benefits outlined in section 5(d) (Benefits) and asked that this was also updated to reflect the new services and amendments added to this revised application. IGARD also asked that section 5(d) was amended to include the date that the benefits were accrued; and, where relevant, that any of the benefits that had already been achieved were moved to the yielded benefits section (section 5(d) (iii) (Yielded Benefits). IGARD noted the reference in section 5(e) to the *"HES Special Terms"* and asked that either a copy of this was uploaded to NHS Digital's Customer Relationship Management (CRM) holder; or that the reference to this document was removed from the application. IGARD queried the statement in section 5(c) "*"…this is not the same thing as linking the Data to other patient level information…"* and asked that either further clarity was provided on this, or that the statement was removed from the application. IGARD noted that the statement in section 7 (Approval considerations) was incomplete and asked that this was completed. IGARD queried if the Data Controllers listed accurately reflected the actual data controllership and recent organisational changes within IQVIA; and asked that section 1 was checked and updated as appropriate to reflect the correct information. IGARD noted that all research studies for bespoke analysis were subject to review by the Independent Scientific and Ethics Advisory Committee (ISEAC) who produced a 'decision log' if approved; and asked that a special condition was added to section 6 (Special Conditions) stating that the applicant was required to provide regular (6-monthly) updates of ISEAC approvals to NHS Digital. IGARD advised that they would wish to review this application again when it comes up for renewal. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To ensure that the application accurately reflects throughout that the Civil Registration data requested is mortality data only.

	2. To update the application throughout to make clear that the data held is for 5 years **plus** the current year. 3. To rephrase the reference to commercial aspects as the "*secondary purpose"* to reformulate in terms that whilst there is a commercial benefit this must be proportionately balanced against benefits to the health and social care system, as outlined in NHS Digital's Commercial Purpose Standard 5(e). 4. To provide further clarity in section 1 and section 5(a) of the new projects including *"understanding therapies"* and *"coding audit"*. 5. To update section 5 to ensure the amendments throughout this section reflect the two new projects (iv) and (v). 6. To update section 5(c) to ensure the outputs accurately reflect the new services and amendments added to this revised application. 7. To update the benefits within section 5(d) to reflect the new services and amendments added to this revised application. 8. To include within section 5(d) the date the benefits were accrued; and, where relevant, to move any of the benefits that have already been achieved to the yielded benefits section (section 5(d) (iii)). 9. To upload a copy of the 'HES Special Terms' to the CRM holder; or to remove the reference to this from section 5(e). 10. To clarify or remove the statement in section 5(c) *"…this is not the same thing as linking the Data to other patient level information…"*. 11. To update the ethics approval information in section 7. 12. To update section 1 to ensure that the Data Controllers listed accurately reflects the actual data controllership and recent organisational changes within IQVIA. 13. To insert a special condition in section 6 stating that the applicant is required to provide regular (6-monthly) updates from the Independent Scientific and Ethics Advisory Committee (ISEAC) approvals to NHS Digital. The following advice was given: 1. IGARD suggested that the applicant may wish to update their Privacy Notice to ensure it reflects the Civil Registration data requested. 2. IGARD advised that they would wish to review this application again when it comes up for renewal.
2.2	<u>IQVIA Solutions UK Limited: Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) secondary care pathway analysis. (Presenter: Louise Dunn) NIC-315134-L9Z6B</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) for the purpose of a study aiming to understand the current treatment pathway and disease burden of patients suffering from nasal polyposis and who undergo a surgical treatment known as nasal polypectomy. The primary objective of the study is to quantify the hospital-based burden of the condition related to chronic rhinosinusitis with nasal polyps (CRSwNP) and the surgical treatment patients undergo in the form of nasal polypectomy. The study will furthermore quantify the initial and subsequent treatment related to hospital attendances and admissions that include codes indicative of CRSwNP diagnosis, the co-morbidity and differential care profiles of patient subgroups based on risk groups, and the cost and wider burden of patient hospitalisations. The application was been previously considered on the 23rd January 2020 where IGARD were unable to make a formal recommendation as there was not a quorum of members able to comment on the application. The following points were raised: to provide the overarching IQVIA application (NIC-373563-N8Z9J) referred to in the application as a supporting document; and to provide a brief summary of how the purposes outlined in that application

	extend to this application; to update section 3(a) to clearly outline that this application is using data provided under another DSA (NIC-373563-N8Z9J); to update the legitimate interest description provided in section 5(a) to expressly state **what** the legitimate interest is and how it relates to the proposed processing; to update section 5(d) to provide clarification as to what extent the research outlined is related to in the re-licensing of an existing drug for a novel use; to clarify within section 5(d) what the expected benefits will be of the research will be in relation to the novel use of an already existing licenced drug; to update section 5(c) to specifically reference how the patient groups are involved and that the outputs will be disseminated to a wide range of patient groups; to update section 5(d) to be clear how this study will specifically benefit the health and social care system; to revise section 5(d) of the application to clarify that the stated benefits are achievable with the data that is being provided; to confirm within section 5 that the funder will not have influence on the outcomes nor attempt to suppress publication of the research; to ensure there is reference within the application to the NHS Digital published 5e Commercial Purpose Standard; and ensure the relevant points outlined in the Standard are addressed, particularly that the benefits to the public are proportionately balanced against the commercial benefits to the (commercial) applicant and (commercial) funder; to update section 7 to complete the sentence *"Ethics approval is not required because…"*. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD discussed deferral point 3 which had not been adequately addressed and noted that the applicant's Legitimate Interest Assessment was quite generic rather than focused on the specific project and asked that this was amended further to reflect the specific processing in relation to the specific project as outlined in the application. IGARD noted that deferral point 10 that was raised previously had also not been adequately addressed, and asked that there was reference within section 5(e) (Is the purpose of this application in anyway commercial?) to the themes covered in the NHS Digital published 5e Commercial Purpose Standard; and to ensure the relevant points outlined in that Standard were addressed, in particular that the benefits to the public were proportionately balanced against the potential commercial benefits also accruing to the pharmaceutical company (Sanofi Genzyme Ltd). IGARD queried the study end date and noted that supporting document 1, the study protocol referenced the end date as being December 2019; IGARD asked that confirmation was provided that the project had been extended and suggested that the protocol was updated to correctly reflect the new extension date. IGARD queried the additional years of data requested and were advised by NHS Digital that for this specific application, ten-years of data was being requested to allow the applicant to gain a more accurate insight from the analyses and that this would be restricted to those patients undergoing polypectomies; and that this would be kept separate from any other IQVIA datasets held by the organisation. IGARD noted the update from NHS Digital and asked that for clarity, section 5(b) (Processing Activities) was updated to reflect that the 10 years of study data would be kept separate to other IQVIA datasets held by the organisation. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD advised that they would wish to review this application again when it comes up for renewal. **Outcome Summary:** recommendation to approve subject to the following conditions:

	1. To ensure there is reference within section 5(e) to the themes covered in the NHS Digital published 5e Commercial Purpose Standard; and ensure the relevant points outlined in the Standard are addressed, particularly that the benefits to the public are proportionately balanced against the commercial benefits accruing to the pharmaceutical company (Sanofi Genzyme Ltd). 2. To amend the Legitimate Interest Assessment to reflect the specific processing in relation to the specific project outlined in the application. The following amendments were requested: 1. To provide further clarity within section 5(b) that the 10 years of study data will be kept separate to other IQVIA datasets held by the organisation. 2. To provide confirmation that the project has been extended and the protocol updated with the new extension date. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. It was agreed the condition would be approved Out of Committee (OOC) by the IGARD Chair.
2.3	<u>NorthWest EHealth Limited: Retrospective data analysis of HES and DID data from patients with Refractory Chronic Cough (RCC) who have given consent for their electronic healthcare records to be used in the analysis of healthcare resource utilisation. (Presenter: Louise Dunn) NIC-290527-P5C0Y</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) and Diagnostic Imaging Dataset (DIDs) data for a feasibility study aiming to increase the understanding of the profile and characteristics of patients with unexplained Refractory Chronic Cough (RCC) by understanding the healthcare resource utilisation (HRU) and treatment patterns of these patients. The primary objective of the initial work is: To determine the outpatient and primary care healthcare costs in the 5-years prior to a diagnosis of RCC, compared to a control cohort, matched by demographics and smoking status. The application had been previously considered on the 19th September 2019 when IGARD had deferred pending: to establish the case for the legitimate interest legal basis; to provide a copy of the Legitimate Interest Assessment (LIA) or significant extracts from this; to amend section 5(a) to clearly set out what the legitimate interests are and how they specifically relate to the processing; to update section 5 to clarify how the specific outputs and expected benefits will practically realise the legitimate interests described; noting that legitimate interest is being relied upon, the applicant should work with NHS Digital on a fair processing notice that does not contain misleading statements and is GDPR compliant; to update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience (for example when referring to *"burden"*); to amend the application throughout to be clear that this application relates to the members of the cohort and not the control group and that the second part of the project that will compare the consented patient data to a control group is not part of this application; to update section 1 to clearly outline the correct Data Controllers; to provide a written explanation why North West EHealth Limited are not considered joint data controllers, in light of the supporting documents provided and the reference in the application to a *"partnership"* with the study sponsors; to be clear what any future application may cover; to be consistent throughout the application when using the terms "*feasibility"* and *"cost-benefit"*; to be clear what the anticipated outputs are for the UK study to as to enable comparisons to the parallel studies in the US and Europe.

	NHS Digital advised IGARD that Merck Sharp & Dohme Limited (MSD) were currently working with colleagues in NHS Digital's Security Team to approve and sign-off their data security arrangements; and confirmed that no data would flow until this had been completed. NHS Digital also advised that in relation to the previous deferral point 5, that the applicant's Privacy Notice required further work in light of legitimate interest being relied upon. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices; and also noted the update from NHS Digital in relation to previous deferral point 5, that this required further work in light of the legitimate interest being relied upon. IGARD asked that the applicant update and publish their Privacy Notice ensuring the points raised as part of NHS Digital's review of their privacy notices were addressed, and before data could flow. IGARD queried the update provided in the application in relation to previous deferral point 6, and asked that further updates were made to section 5 (Purpose / Methods / Outputs) to ensure it was written in language suitable for a lay reader and that consideration was given to a patient audience, for example making reference to the '*cost of the condition*' rather than the '*cost of the patient*'. IGARD noted that updates had been provided in relation to previous deferral point 7, however asked that wherever *"control data"* was referred to, specifically at the beginning of section 5(a) (Objective for Processing), that this was updated to be clear that the '*control data*' would be provided by Salford Integrated Record (SIR), since it was not clear. IGARD noted the update from NHS Digital in respect of the ongoing work with Merck Sharp & Dohme Limited (MSD) and agreed with NHS Digital that before any data flowed, that NHS Digital's Security Team need to approve and sign-off the data security arrangements. IGARD noted that MSD would not have general access to any data for this application, however that they may require access for audit purposes only; and asked that a special condition was added to section 6 (Special Conditions) clarifying this and also that if access was required for the purpose of an audit, that this would take place within Manchester University NHS Foundation Trust premises; and that no data would flow outside of England and Wales. IGARD noted that the Principal Investigator's name was referenced within the application and asked that this was updated to ensure all references to their name were removed. IGARD queried the statement in section 5(e) (Is the purpose of this application in anyway commercial?) to *"…there will be no benefit to the public"* and asked that this was revised to reflect the feedback provided i.e. to state that even if MSD do not develop further drug therapies, that there were other benefits to the public as outlined elsewhere in the application (for example the Principal Investigator gaining a greater understanding of the care cycle). IGARD advised that they would wish to review this application again when it comes up for renewal. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. NHS Digital Security to approve and sign-off the data security arrangements for Merck Sharp & Dohme Limited (MSD), and before data can flow. 2. The applicant to update and publish their Privacy Notice ensuring the points raised as part of NHS Digital's fair processing criteria for privacy notices are addressed. 3. To insert a special condition in section 6 stating that MSD will not have general access to the data for this application, and if access is required for audit purposes, that this will

	take place within Manchester University NHS Foundation Trust premises; and that no data will flow outside of England and Wales. The following amendments were requested: 1. To amend the beginning of section 5(a) (and wherever control data is referred to) to be clear that the 'control data' will be provided by Salford Integrated Record (SIR). 2. To further update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience (for example referring to the cost of the condition rather than the cost of the patient). 3. To update the application to ensure any reference to the Principal Investigator's name is removed. 4. To revise the statement in section 5(e) *"…there will be no benefit to the public"* to state that even if MSD do not develop further drug therapies there are other benefits to the public as outlined elsewhere in the application (for example the Principal Investigator gaining a greater understanding of the care cycle). The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. It was agreed these conditions would be approved Out of Committee (OOC) by the IGARD Chair.
2.4	<u>Medicines and Healthcare Products Regulatory Agency (MHRA): Clinical Practice Research Datalink (CPRD) Routine Linkages Application (Presenter: Kimberley Watson / Louise Dunn) NIC-15625-T8K6L</u> **Application:** This was an amendment application to change the territory of use to 'worldwide'; The application also allows for the onward sharing of data through sub-licencing. The Clinical Practice Research Data-link (CPRD) is a centre of the Medicines and Healthcare products Regulatory Agency (MHRA) an executive agency of the Department of Health and Social Care (DHSC), which regulates medicines, medical devices and blood components for transfusion in the UK. 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. **Discussion:** IGARD and NHS Digital had a lengthy discussion as to why the data requested was considered 'anonymised' when released under sub-licence and therefore outside the scope of the General Data Protection Regulation (GDPR), especially in light of the references throughout the application that the data requested was "*personal data*". NHS Digital advised IGARD that the data released by them (NHS Digital) to CPRD would be pseudonymised and would qualify as personal data; however CPRD had advised NHS Digital that before this data was released by CPRD under any sub-licencing arrangements, this data would be 'anonymised' and therefore NHS Digital's view was that this data would fall outside the scope of GDPR. IGARD and NHS Digital discussed why the CPRD data release might be considered anonymised. IGARD noted the references to *"pseudonymised"* and *"personal data"* within the application. In addition, NHS Digital advised IGARD that following submission of the papers for IGARD's review, there had been further correspondence internally that supported the CPRD's analyses that the data to be provided under sub-license was 'anonymous'. IGARD expressed concerns over whether there was a possibility of the 'anonymised' data being re-identified following the release of this data under sub-licensing arrangements and the reputational risk to NHS Digital

	by treating this data as anonymous. To further support the discussion on this issue, IGARD requested sight of any internal advice to DARS that supported CPRD's analysis. IGARD requested further evidence to support the view that the data released would be truly *"anonymised"* and asked for an analysis in support of this hypothesis for example an analysis that shows how CPRD's policy on anonymisation maps against the GDPR / any guidance from the Information Commissioners Office (ICO) (such as the ICO Code of Practice on Anonymisation noting this was being updated by the ICO but is flagged by the ICO on their website as a starting point for such analysis). IGARD noted ongoing media interest and advised NHS Digital that that they had requested and had not yet had sight of CPRD's response to the letter from MedConfidential issued in 2019, that outlined the steps taken to anonymise data since the questions raised about anonymisation had in essence been previously raised by IGARD numerous times in the past across various MHRA / CPRD applications IGARD noted the amendment to change the territory of use from England and Wales to 'worldwide' and noted that in order to support this amendment amongst other things, clarification would need to be provided as to why the data was considered 'anonymised' and therefore outside the scope of GDPR. IGARD noted that information provided in section 5(d) (Benefits) that made specific reference to European and worldwide studies that had used CPRD data, however queried what the benefits to the health and social care system specifically within England and Wales were, and how these would be assessed following the data being provided worldwide under sublicensing; and asked that further information was provided outlining this. IGARD also suggested the applicant may wish to consider utilising mechanisms used by other applicants for NHS Digital data, who then go on to share further or via sublicence; for example the CPRD Oversight Committee could ask the sublicence applicants to outline how their proposed outputs would benefit the health and care system in England and Wales. IGARD queried if the applicant was aware of NHS Digital's expectation in relation to the scope of audits carried out by CPRD; and asked that NHS Digital provided them with further guidance which could include an 'audit template' to support any future audits. IGARD suggested that as NHS Digital was the Data Processor for part of the data processing, that they may wish to consider a Data Processing Agreement was put in place between them and CPRD, that may be separate to this application. **Outcome Summary:** IGARD were unable to make a recommendation as the relevant documents, essential for IGARD's review, were not available 1. In light of the amendment requesting worldwide territory of use (cf. England and Wales), IGARD asked for clarification as to why the data was considered 'anonymised' and therefore outside the scope of GDPR. 2. IGARD requested sight of any internal advice to DARS, supporting CPRD's analysis that the data provided under sublicence is 'anonymous'. 3. IGARD requested further evidence to support the view that the data released would be truly *"anonymised"* and asked for an analysis in support of this hypothesis for example an analysis that shows how CPRD's policy on anonymisation maps against the GDPR / any guidance from the Information Commissioners Office such as the currently under review ICO Code of Practice on Anonymisation (noting that although the document was currently under review it was flagged by the ICO on their website as a starting point for such analysis) and Article 29 Working Group guidelines on anonymisation.

	4. To provide further information about how benefits to health and social care within England and Wales will be assessed for data provided worldwide under sub-licence. 5. IGARD suggested utilising mechanisms used by other applicants for NHS Digital data who then go on to share further or sublicence - for example the CPRD Oversight Committee could ask the sublicence applicants to outline how their proposed outputs will benefit the health and care system in England and Wales. 6. NHS Digital to provide further guidance to the applicant on the expectations of an audit being carried out; and to provide the applicant with an 'audit template'.
2.5	<u>Imperial College London: Effectiveness and Value for Money of Prescribed Specialised Services Commissioning for Quality and Innovation (CQUIN) (Presenter: Stuart Blake) NIC-172334-W0G2L</u> **Application:** This was an amendment application to 1) add an additional purpose – to developing a methodology to model how knowledge of health policies diffuses amongst health professionals; 2) to add the sensitive field Consultant Code (instead of the previously provided PCONSULT pseudonymised consultant code) so that the applicant can link with General Medical Council (GMC) registry data as part of the above purpose; and 3) to add an additional year of HES data (2018/19). The purpose is for a programme to improve the healthcare quality of specialised services (rare and complex conditions) in NHS hospitals. **Discussion:** IGARD noted the amendment to add the sensitive field Consultant Code to the data and queried if this was still pseudonymised, NHS Digital confirmed this was pseudonymised and could only be linked to the GMC code. IGARD queried if the consultant codes were required for **all** years of data, not just the current year and asked that clarification was provided in section 1 confirming this. IGARD queried the scope of the research being undertaken and the potential ethical issues raised by the study and asked that section 5 (Purpose / Methods / Outputs) was updated clearly outlining the scope of the research. IGARD also asked the applicant addressed any potential misuse of data outputs or potential use of data for any reasons other than those clearly set out in the application. In addition, IGARD also asked that section 1 (Abstract) and Section 5(a) (Objective for Processing) needed to be expanded to include further information on the purpose and scope, including a more explicit description of the study and suggested that the information in section 5(d) (Benefits) could be referenced. IGARD also asked that section 5(a) was further updated to outline the purpose of the new research and align this with information provided in section 5(d). IGARD noted that section 7 (Approval Considerations) needed updating further to address the new processing outlined in the application and asked that confirmation was provided that Ethics approval was **not** necessary for this study, as well as any local / University-based Ethics approval. IGARD asked that if any form of ethical review was required, that evidence of such approval was provided. IGARD noted that section 5(c) (Specific Outputs Expected) stated *"The study have invited two patient representatives to join their advisory group…"* and suggested that consultant representatives or a representative body (e.g. the BMA) may be appropriate on the advisory group as well. IGARD asked that information was provided outlining any discussions that may have taken place with any industry bodies, such as the British Medical Association (BMA) about the potentially sensitive nature of this research; and that a plan was set out (if this had not already taken place) for engaging with the relevant industry bodies, (e.g. the BMA), to ensure that the perspectives of the Consultants subject to the study had been considered. If these discussions had already occurred, a summary of the steps taken was requested. In

	addition, consideration should be given to how the outputs of the study were disseminated appropriately. IGARD suggested that the applicant may wish to consider a wider discussion, if this had not already taken place, for example with the General Medical Council (GMC) and / or the BMA to investigate whether the outputs of the research could be used to reduce differential achievement between consultants / widen access to effective social networks so as to improve consultant performance. IGARD noted the additional purpose had been funded by the Medical Research Council (MRC) grant and asked that the MRC application, a copy of the protocol or any other supporting documentation was provided as supporting evidence in relation to the MRC funding obtained. IGARD noted that an Article 9 legal basis had been provided, but queried the Article 9 of the General Data Protection Regulation (GDPR) legal basis referenced within the application was the most appropriate and suggested that the applicant may wish to consider if an alternative Article 9 legal basis would be more appropriate for the research outlined. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD also asked that this was reviewed to ensure the new limb of the study and processing was adequately addressed and to update section 1 to clarify this; and to ensure all links to the privacy notice were functioning. IGARD noted the references in section 5(b) *"…to estimate how information can pass through both targeted and non-targeted agents."* and asked that a further explanation of this was provided. **Outcome Summary:** recommendation to approve subject to the following conditions: (IGARD reserve the right to consult with NHS Digital's Caldicott Guardian on the assessment of the responses to the conditions for this application): 1. To update section 5 throughout to address the potential ethical issues raised in the study by clearly outlining the scope of the research being undertaken and addressing any potential misuse of data outputs or potential use of data for any reasons other than those clearly set out in the application. 2. To (a) provide information about any discussions that may have taken place with any industry body such as the BMA about the potentially sensitive nature of this research and (b) set out a plan for engaging with relevant industry bodies, for example the BMA, to ensure that (i) the perspectives of the Consultants subject to the study are considered and (ii) the outputs of the study are disseminated appropriately. 3. To provide the Medical Research Council application/a copy of the protocol or any other supporting document that was provided as supporting evidence in relation to the MRC funding obtained. 4. To update the Ethics approval section of the application to address this new processing; to provide clear confirmation that Ethics approval was not necessary for this study (including any local/university-based Ethics approval). If, in fact, any form of ethical review was required, to provide evidence of such approval. The following amendments were requested: 1. To explain the purpose and scope of the study in the abstract and section 5(a) by reference to the helpful explanatory form of wording used in section 5(d) of the application. 2. To consider if an alternative Article 9 legal basis would be more appropriate for the research outlined (e.g. service review of scientific research). 3. To review in line with NHS Digital's fair processing notice check of the applicant's Privacy Notice to ensure the new limb of the study and processing is adequately

	addressed and to update section 1, plus ensure all links to the privacy notice are functioning. 4. To amend section 5(a) to further outline the purpose of the new research and align with information provided in section 5(d). 5. To provide clarification that the consultant codes is for **all** years of data, not just the current year. 6. To provide a further explanation within section 5(b) on the reference to *"targeted and non-targeted consultants".* 7. To update section 1 to provide a more explicit description of the study and align with information provided in section 5(d). The following advice was given: 1. IGARD suggested that the applicant may wish to consider a wider discussion, for example with the GMC and/or BMA to investigate whether the outputs of the research could be used to reduce differential achievement between consultants/widen access to effective social networks so as to improve consultant performance. It was agreed the conditions would be approved OOC by IGARD members.
3 **3.1**	AOB: **Mental Health of Children and Young People (MHCYP) Survey** NHS Digital provided IGARD with an update on the latest position with the MHCYP survey, which provides data on the prevalence of mental health disorders in children and young people aged 2-19 years living in England. NHS Digital confirmed that there was ongoing work internally within NHS Digital and the Department for Health and Social Care to obtain a full Direction and that further information would be provided in due course. 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 31/01/20

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)
None						

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the quarterly Oversight and Assurance Report.

In addition, a number of applications were approved by NHS Digital under class action (addition of Liaison Financial Service and Cloud storage):

- NIC-55710-W8F8C NHS West Essex CCG
- NIC-47180-P3Z1Q NHS Bolton CCG
- NIC-41522-S6G4K NHS Redditch & Bromsgrove CCG
- NIC-186883-L6C8YNHS Birmingham & Solihull CCG
- NIC-147942-N8J6Y NHS South West Lincolnshire CCG
- NIC-352298-S8K3P NHS Lincolnshire West CCG
- NIC-353691-D9Z9G NHS South Lincolnshire CCG
- NIC-147936-X6M4N NHS Lincolnshire East CCG