Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 23rd April 2020

In attendance (IGARD Members): Paul Affleck, Maria Clark, Nicola Fear (2.3 onwards), Kirsty Irvine (Chair), Imran Khan.

In attendance (NHS Digital): Dave Cronin, Louise Dunn, Karen Myers, Vicki Williams.

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

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 9th April 2020 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Data Applications**
2.1	2020 Delivery: Benchmarking operational performance and patient cohort demand on the NHS national service structure (Presenter: Louise Dunn) NIC-26646-M9Q0J **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data, which has been requested by the applicant for the purpose of being able to provide its clients with higher quality and more specific answers regarding the identification, assessment and quantification of opportunities for NHS services to improve their quality and efficiency. The clients (NHS organisations) will be able to make better decisions on how to spend public money to benefit patients, in some cases these decisions are critically important, for example to the viability of a hospital service. The application was been previously considered on the 16th January 2020 when IGARD had deferred pending: the applicant to provide a revised fair processing notice and to ensure that it is compliant with the notice requirements under the GDPR, particularly with reference to the legitimate interests relied upon; to update the application throughout to ensure the correct legal entity is referred to as noted on the Companies House website; to update section 5(a) when reference is made to whom the applicant will not be working by including the wording "For the avoidance of doubt…" before the list of prohibited entities; to provide more specific details of the projects for which the applicant will be using the requested data; to remove any reference to general "projects" or any other generic use of the data (i.e. data may only be used for detailed and specific projects); to clarify how the HES data requested will improve the outputs and impact of each of the projects; to clarify what aspects of the data sets will be used for each project (e.g. date range, geographic spread, HES fields); to clarify for each project how data minimisation will be addressed (rather than the current generic wording in section 5); to provide further specific details of the legitimate interest relied upon and how it specifically relates to the purpose of the proposed processing, and providing detailed consideration of how the proposed processing links to the three limbs of legitimate interest assessment; to update section 5(c) and 5(d) to provide more detail with regard to the outputs and benefits (again in respect of each specific project); to provide further clarity in section 5(e) outlining how the activities outlined are commercial and how this is balanced as against the benefit to Health and Social Care, as required in the NHS Digital published Commercial Purpose Standard.

	NHS Digital advised IGARD that following IGARD's review of the application on the 16th January 2020, and following further discussions with the applicant, that significant amendments had been made to the application to refine the request for data to one project, and as a result not all of the previous points raised by IGARD were now relevant to this application. NHS Digital also noted that the applicant had been advised that any future data required for any other purpose would need to be requested via a separate application via the usual NHS Digital process. **Discussion**: IGARD noted that the application had been updated, where relevant to reflect the comments previously made but noted that the application had been significantly updated since it had been last presented to IGARD. IGARD queried the role of The British Red Cross and whether they should be considered a joint Data Controller and were advised by NHS Digital that discussions had taken place with the applicant on this issue and NHS Digital were content that The British Red Cross should not be considered a joint Data Controller due to them being a client of the applicant. IGARD noted this analysis and asked that for audit purposes, section 1 (Abstract) was updated clarifying why The British Red Cross was not considered a joint Data Controller. IGARD noted the references in section 5(b) (Processing Activities) to "clients" and asked that this was amended to clarify that the processing permitted under this application related only to the work that the applicant was doing to support The British Red Cross, and that any other use of the data for any other clients would be subject to an amendment of the Data Sharing Agreement (DSA). IGARD also noted the reference(s) in section 1 to the applicant's clients being "NHS organisations" and asked that this was updated to ensure it only referred to The British Red Cross being a client. IGARD noted the references throughout the application to the data provided by NHS Digital not being linked and queried if, in light of this, that the stated outputs were achievable without linking the data that was being provided to any other data sets or qualitative information, and that confirmation of this be provided. IGARD noted that the application was inconsistent when referring to the cohort that was being studied, and asked that the application was updated throughout to clarify that the specific cohort were those "high intensity" patients who had attended A&E five or more times within a specific time period. In addition, IGARD also noted that the data minimisation column in section 3(b) (Additional Data Access Requested) was not limited to the cohort outlined and asked that this was updated to reflect that the data requested was only for those high intensity users, attending A&E five times or more in 2015/16. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, and asked that a special condition was inserted in section 6 (Special Conditions) expressly stating that no NHS Digital data would flow until an updated Privacy Notice that was compliant with the requirements under the General Data Protection Regulation (GDPR) had been published. IGARD noted the language used throughout the application, including the Legitimate Interest Assessment (LIA), that appeared to incorrectly suggest that the data was not "personal data" and asked that the application was updated to remove these references. IGARD noted the revised information provided at the end of section 5(a) (Objective for Processing) in relation to the legitimate interests and asked that for ease of reference this was moved to the beginning of this section, including the reference to the specific project.

	IGARD queried the statement in section 5(e) (Is the Purpose of this Application in anyway Commercial?) that stated 2020 Delivery Limited would be *"…incurring the costs associated with this specific dataset…"* and asked that this was reviewed in light of the commercial aspects if this was, for example, not a charitable donation. IGARD noted the reference in section 1 stating that NHS digital were satisfied that the Security documentation demonstrated the level of security and governance in place, and asked that this was updated to state *"**required** level of security"*. IGARD suggested that the applicant may wish to consider (if they haven't already) the level of Patient and Public Involvement (PPI) currently, and in the future, which may take the form of membership of steering groups or other such initiatives to involve the community. IGARD suggested that they would wish to review this application again when it comes up for renewal and that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To confirm that the stated outputs are achievable without linking the data that is being provided to any other data sets or qualitative information. 2. To update the data minimisation column in section 3(b) to reflect that the data requested is only for the cohort of those high intensity users attending A&E five or more times in 2015/2016. The following amendments were requested: 1. To update the application throughout to clarify that the specific cohort been studied are those attending A&E five or more times in a specific time period. 2. To insert a special condition in section 6 expressly stating that no data will flow until an updated Privacy Notice that is compliant with the notice requirements under the GDPR has been published. 3. To amend section 5(b) to clarify that the processing permitted under this application relates only to the work that the applicant is doing to support The British Red Cross, and that any other use of the data for any other clients will be subject to an amendment of the application. 4. To update the application (in both the LIA assessment and throughout) to remove any references to the data not being *"personal data"*. 5. To update section 5(a) to ensure the revised legitimate interest paragraph (including reference to the specific project) is moved from the end of the section to the beginning of this section. *6.* To review the statement in section 5(e) that the applicant is *"…incurring the costs associated with this specific dataset…".* 7. To amend section 1 to ensure the applicant's 'clients' refers only to The British Red Cross and to remove any reference(s) to *"NHS organisations"*. 8. To update section 1 to clarify why The British Red Cross was not considered a joint Data Controller. 9. To update the reference in section 1 to state *"**required** level of security"*. The following advice was given: 1. IGARD suggested that the applicant may wish to consider (if they haven't already) the level of PPI currently, and in the future, which may take the form of membership of steering groups or other such initiatives to involve the community. 2. IGARD advised that they would wish to review this application again when it comes up for renewal.

	3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. It was agreed the conditions would be approved Out of Committee (OOC) by the IGARD Chair.
2.2	<u>National CJD Surveillance Unit – University of Edinburgh: MR694 - This is an application to extend & renew an existing DSA in order to authorise the on-going retention and reuse of data that exists under NIC 148232 -TRANSFUSION MEDICINE EPIDEMIOLOGY REVIEW (Presenter: Louise Dunn) NIC-148232-CPHLL</u> **Application:** This was a renewal and extension application for identifiable Medical Research Information Service (MRIS) data for the purpose of the Transfusion Medicine Epidemiology Review (TMER) project, set up in 1997 with the aim of investigating whether Creutzfeldt Jakob Disease (CJD) and its variant form (vCJD) may be transmitted via the blood supply. This study helped identify, in 2004, the first case of transfusion transmitted infection of vCJD – in a patient who had received blood from a blood donor who had, subsequent to the donation, later gone on to develop vCJD. This findings, along with later reports and publications from the study have informed health guidance and policy decision making in the UK and overseas. **Discussion:** IGARD noted this was an important long running study. IGARD queried the considerations taken into account when seeking s251 support from the Health Research Authority's Confidentiality Advisory Group (HRA CAG) and the conclusion that the activity was for surveillance, and asked that further background information was provided. In addition, IGARD also queried if, for example, Regulation 3, Health Service (Control of Patient Information) Regulations 2002 had been considered as an alternative route to s251 and that further clarification was provided. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices, and asked that a special condition was inserted in section 6 (Special Conditions) expressly stating that no NHS Digital data would flow until an updated Privacy Notice that was compliant with the notice requirements under the General Data Protection Regulation (GDPR) had been published. IGARD noted the discrepancy between the cohort figures referenced in the application (particularly section 3(a) (Data Access Already given)) and the supporting documents (particularly SD1.2) provided and asked that an explanation was provided on the difference in cohort sizes; or asked that if the application was incorrect that this was updated to reflect the correct cohort size. IGARD queried the statement in section 5(d) (Benefits) that data would flow to the UK Blood Service (UKBS) and queried the source of this data flowing to UKBS and asked for clarification. In addition, IGARD also queried the legal basis for this data to flow and that confirmation be provided. IGARD noted the information provided in supporting document 7, the 2018 Research Contract between the Department of Health and Social Care and the University of Edinburgh that stated the applicant should produce and publish a full Patient and Public Involvement (PPI) and Engagement Strategy, and make it accessible to the public within twelve months of the commencement date. IGARD asked that this Strategy was provided as a supporting document and that section 5 (Purpose / Methods / Outputs) was updated describing what PPI steps had been taken. IGARD queried the information provided in the application of the last recorded transmission from a blood product and were advised by NHS Digital that this was 2007. In addition, IGARD also queried the date of the last vCJD diagnosis and were advised by NHS Digital that this

	was 2016. IGARD noted the dates confirmed by NHS Digital and asked that the application was updated to reflect this information. IGARD noted a reference within supporting document 1.5, the NHS Health Research Authority (HRA) letter that referred to Welsh data and asked that confirmation was provided of how the handling of the Welsh data had been addressed. A number of technical phrases and words were noted within section 5 and IGARD suggested that this public facing section be updated to ensure that technical language was used only where necessary; and where necessary, that it also had a further supportive explanation in language suitable for a lay reader. IGARD queried the references within section 1 (Abstract) to *"Co-investigator"* and asked that this was updated to remove these references and to correctly reflect that the University of Edinburgh was the sole Data Controller **Outcome Summary:** recommendation to approve subject to the following condition: 1. To provide further background information or clarification of the consideration taken into account when seeking s251 support and the conclusion that the activity is for surveillance; and clarification if, for example Regulation 3, Health Service (Control of Patient Information) Regulations 2002 was considered as an alternative route. The following amendments were requested: 1. To insert a special condition in section 6 expressly stating that no data will flow until an updated Privacy Notice that is compliant with the notice requirements under the GDPR has been published. 2. To provide an explanation on the significant difference in cohort sizes between the application and supporting documents; or to update the application to reflect the correct cohort size. 3. To clarify the source of data flowing to UKBS as referred to in the final paragraph in section 5(d) and to confirm the legal basis for this data flow. 4. To provide as a supporting document the PPI strategy and to update section 5 to describe what PPI steps have been taken. 5. To amend the application to accurately reflect that 2007 was the last recorded transmission from a blood product and 2016 was the last diagnosis of vCJD. 6. To provide confirmation of how the handling of the Welsh data has been addressed. 7. To update section 5 to ensure the use of technical phrases is used only where necessary and where it is necessary to also provide a further supportive explanation. 8. To update section 5(c) to ensure all the incomplete sentences are completed as necessary. 9. To update section 1 to reflect that the University of Edinburgh is the sole Data Controller, and to remove all references to *"Co-Investigator"*. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
2.3	Group Application 2 CCG's[1]: DSfC - NHS Devon CCG and NHS Kernow CCG - Commissioning (Presenter: Louise Dunn) NIC-348357-W0P1W **Application:** This was a new application for 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),

[1] NIC-348357-W0P1W NHS Devon CCG and NHS Kernow CCG

	National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (CRD) National Diabetes Audit (NDA) and Patient Reported Outcome Measures (PROMs). The purpose of the application is to provide intelligence to support the commissioning of health services. NHS Digital advised IGARD that the Data Protection Act (DPA) Registration expiry data for NHS Kernow CCG had expired and that following submission of the application for IGARD's review it had been updated to reflect the new date. In addition, NHS Digital noted that the DPA registration date for NHS Devon CCG was due to expire and that this would be updated within the application accordingly. **Discussion:** IGARD noted the update from NHS Digital in relation to the updated DPA Registration expiry dates for NHS Kernow CCG and NHS Devon CCG and the relevant amendments to the application to reflect the new dates. IGARD noted the General Data Protection Regulation (GDPR) legal basis outlined in section 1 (Abstract) and queried if this applied to both Data Controllers and were advised by NHS Digital that this was correct; IGARD asked that section 1 was updated clarifying that the legal basis applied to both CCG's. IGARD queried if the applicants had other active NHS Digital Data Sharing Agreements (DSA) and, if so, asked that section 1 was updated to include any reference(s) to these DSAs. IGARD noted and endorsed NHS Digital's review that the applicants did **not** meet NHS Digital's Standard for privacy notices. **ACTION:** separate to this application, it was agreed that IGARD and NHS Digital would review the current CCG precedent templates at a future IGARD meeting. **Outcome Summary:** recommendation to approve 1. To amend section 1 to clarify that the stated legal basis applies to both Data Controllers. 2. To update section 1 to include references to the applicant's other active NHS Digital DSAs.
2.4	<u>NHS Gloucestershire CCG: DSfC - NHS Gloucestershire CCG / Gloucestershire County Council - Population Health (Presenter: Louise Dunn) NIC-343158-Z2L4D</u> **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS+), 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), Civil Registries Data (CRD), National Cancer Waiting Times Monitoring Data Set (CWT), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Diagnostic Imaging Data Set (DID). The purpose of the application is to provide intelligence to support the commissioning of health services. The application was been previously considered on the 26th March 2020 when IGARD had deferred pending: to update section 1 and section 5(a) with a further detailed description of Optum Health Solutions UK Limited and the activities they carry out; to revise the application throughout to ensure that any references to *"Risk Stratification"* activities are for the purpose of commissioning; and to explain why, for example, there is reference to *"identification of specific patients"*, or remove such references if they are not relevant to the purpose of commissioning; to update section 1 and section 5 with confirmation of who will be receiving the linked data and clarification of what data is being linked; to revise the references in section 5(b) to a *"specific named individual"* and consider replacing this with "specific named role"; and to clarify that this

	role will be separate from any other roles that may lead to a conflict; the applicant should work with NHS Digital on a Privacy Notice that is GDPR compliant; to update section 5(b) to further expand on the data minimisation criteria outlined; to update section 1 with a more detailed description of how the other Data Sharing Agreements referenced link together and assurance that there is no duplicate flow of data; to provide further confirmation in section 1 of what is happening to the data under NIC-182332. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. As previously discussed, IGARD again queried the role of Optum Health Solutions UK Limited, noting they were referenced throughout the application; and asked that section 1 (Abstract) and section 5(a) (Objective for Processing) were updated with a further detailed description including confirmation of the activities Optum Health Solutions UK Limited carry out. IGARD also queried again, the reference in section 5(b) (Processing Activities) to a *"specific named individual"* and asked that this was revised and that consideration was given to replacing this with *"specific named role";* and that clarification was provided that this role would be separate from any other roles that may lead to a conflict. IGARD noted the Risk Stratification element to the application for the CCG and that the CCG received risk stratification data under another Data Sharing Agreement (DSA), however this application was for the purpose of Commissioning and asked that the application was updated to accurately reflect how this Commissioning application had a Risk Stratification element. In addition IGARD noted the information provided in section 1 that stated the CCG may be alerted to patients through the commissioning processing who would benefit from further support and was able to use other datasets held under other DSAs to identify individuals through this process; and asked that section 5 (Purpose / Methods / Outputs) was updated clarifying this. IGARD noted that the processing activities outlined in the application were not accurately reflected in the data flow diagram provided, and asked that the data flow diagram was updated to accurately reflect the correct information. IGARD noted that the applicant had been provided with feedback from NHS Digital on their privacy notice and as yet had not provided or published an updated version, and therefore endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To update the application to reflect how this Commissioning application has a Risk Stratification element. The following amendments were requested: 1. To update section 1 and section 5(a) to include a description of Optum Health Solutions UK Limited. 2. To revise the remaining reference in section 5(b) to a *"specific named individual"* and consider replacing this with "specific named role"; and to clarify that this role will be separate from any other roles that may lead to a conflict. 3. To update section 5 to clarify that the CCG may be alerted to patients through the commissioning processing who would benefit from further support and is able to use other datasets held under other DSAs to identify individuals through this process. 4. To update the data flow diagram to accurately reflect the processing described in the application.

	It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
2.5	University of Oxford: An evaluation of knee arthroplasty fixation in an evolving challenging population (Presenter: Dave Cronin) NIC-316443-V5Z4Y **Application:** This was an amendment application for 1) the variable 'sex' data to be supplied to NHS Digital by Northgate Public Services, forwarded on to the University of Oxford and used in analyses (the previous Data Sharing Agreement (DSA) did not mention this variable); and 2) the full set of HES records (excluding maternity, fetal and psychiatry fields) are required to accurately profile the patients' past medical history. The purpose is for an evaluation of knee arthroplasty fixation in an evolving challenging population. The study team are aiming to help deliver more patient specific care and improve outcomes, and also guide surgical provision for healthcare provider and help patients make more informed decisions. NHS Digital advised IGARD that due to issues with how knee replacements were coded, approximately 25,000 patients were not identified, and therefore additional data was now being requested. NHS Digital also noted a number of omissions and errors within the application that were in the process of being amending, this included 1) section 5(a) (Objective for Processing) required some minor updates to reflect the amendments to the application to accurately reflect the data required; and 2) an update to section 5(a) to reflect accurate information on the Office of Population Censuses and Surveys (OPCS) codes. **Discussion:** IGARD noted the update from NHS Digital on the justification of the additional data requested; and the omissions and errors outlined in section 5(a) that were in the process of being amended. IGARD noted that the volume of data requested had changed and increased substantially following submission of the revised application and asked that a clear justification was provided for the quantum of data requested in line with NHS Digital's Data Minimisation Standard (3), with confirmation of how each of the points in the Standard had been considered by the applicant and addressed. IGARD queried the condition set out in supporting document 8, the National Joint Registry (NJR) approval letter that stated *"It was unclear the reason for requesting cause of death. The applicants are advised to remove this data item prior to submission to the data controller for final approval."* and asked that confirmation was provided that this did not prohibit NHS Digital from flowing mortality data. IGARD noted that the reference to the General Data Protection Regulation (GDPR) Article 9 legal basis differed throughout the application and asked this was updated to ensure the correct legal basis was consistently referenced throughout the application. IGARD noted that the applicant had a revised privacy notice that was ready for publishing, however suggested that this was reviewed further to specifically address point 17 of the Information Commissioner's Office (ICO) checklist / NHS Digital Transparency Standard to ensure it was suitable for a lay audience. **Outcome Summary:** recommendation to approve subject to the following conditions: 1. To provide written justification for the quantum of data requested, in line with NHS Digital's Data Minimisation Standard 3, confirming how each of the points in the Standard have been considered and addressed.

	2. To provide confirmation that the condition of the NJR approval in SD8 does not prohibit NHS Digital from flowing mortality data. The following amendments were requested: 1. To update the application throughout to ensure the correct Article 9 GDPR legal basis is consistently referenced. 2. IGARD suggested that the applicant's Privacy Notice is reviewed further to specifically address point 17 of the ICO checklist / NHS Digital Transparency Standard to ensure it is suitable for a lay audience. 3. To update section 5a to correct any omissions or errors, as notified by NHS Digital. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.6	<u>Sandwell and West Birmingham Hospitals NHS Trust: MR1492 Birmingham and Black Country Atrial fibrillation cohort study follow up (Presenter: Dave Cronin) NIC-331733-T2K1Z</u> **Application:** This was a new application for identifiable Medical Research Information Service (MRIS) data and was submitted to IGARD for advice on whether the participant consent is sufficient to meet the duty of confidentiality requirement. The purpose is for a prospective longitudinal observation study, aiming to improve understanding of Atrial Fibrillation (AF). AF is a condition affecting 3% of the population in which the heart rate becomes irregular and in some cases is very fast, a complication of AF is heart failure. **Discussion:** IGARD welcomed the application which came for advice on whether the participant consent is sufficient to meet the duty of confidentiality requirement and without prejudice to any additional issues that may arise when the application is fully reviewed. In respect of the participant consent materials, IGARD advised that the processing outlined in supporting document (SD) 2.1 version 4 of the earlier consent materials was not consistent with the consent participants gave and therefore not compatible with the proposed processing; and suggested that the applicant may wish to consider seeking s251 support for this specific cohort. IGARD advised that the processing outlined in SD2.2, version 7 of the later consent materials, could be expressed more clearly but was compatible with the proposed processing in particular for the request of mortality data and exits from the NHS. However SD2.2 version 7 may not be compatible for other data flows or linkage (for example HES data) for living members of the cohort and any additional data requested may need to have a corresponding improvement in transparency materials, for example by way of a newsletter to study participants. In respect of the application presented, IGARD noted the applicant should provide a privacy notice that was compliant with the notice requirements under the General Data Protection Regulation (GDPR) and suggested that they work with NHS Digital to provide a compliant privacy notice. IGARD queried the reference within the application to *"managing patients"* and asked that this was amended to state *"managing conditions"*. IGARD noted the information provided in SD1, the funding letter from the University of Birmingham, that stated funding was provided through a number of organisations including a European Union consortium grant; and suggested that further details of the funding and the funding organisations was provided within Section 5 of the application.

	IGARD noted the reference within the application to the 'CATCH ME Project' and suggested that the applicant may wish to consider (if they haven't already) bringing this to the attention of the study participants. **Outcome:** IGARD welcomed the application which came for advice on the consent materials and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. IGARD advised that the processing outlined in version 4 of the consent materials was not consistent with the consent participants gave; and suggested that the applicant may wish to consider seeking s251 support for this specific cohort. 2. IGARD advised that the processing outlined in version 7 of the consent materials was compatible for the request for mortality data and exits from the NHS, however it may not be compatible for other data flows or linkage (for example HES data) for living members of the cohort and any additional data request may need a corresponding uplift in the consent materials for example by way of a newsletter to study participants. In relation to the application, the following observations were made: 1. The applicant should work with NHS Digital on a Privacy Notice that is GDPR compliant. 2. To amend the application throughout to ensure any reference to "managing patients" is amended to "managing conditions". 3. IGARD suggested that further details with regard to the funding and funding organisations be provided, including particular consideration of the EU funding. 4. IGARD suggested that the applicant may wish to consider (if they haven't already) bringing the CATCH ME Project to the attention of the study participants.
3	<u>NIC-368233-L2N0W McKinsey & Company, Inc. United Kingdom – Briefing Paper (Presenter: Dave Cronin)</u> The briefing paper was to provide IGARD members with an overview of the historical information relating to this application following IGARD's last review on the 4th July 2019; and in advance of the application returning for a further review at next week's IGARD meeting (30th April 2020). IGARD welcomed the briefing paper and thanked NHS Digital for providing this in advance of the application being fully reviewed by IGARD next week.
4	<u>COVID-19 update</u> To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and COPI regulation urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process. The ratified action notes from Tuesday 21st April 2020 can be found attached to these minutes as Appendix B. IGARD noted that there were no additional COVID-19 related items to discuss at this week's meeting.
5	<u>AOB:</u> 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.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 17/04/20

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)
NIC-79526-V8F2X	University of East Anglia	02/04/2020	1. To clarify why the University of East Anglia is considered the sole Data Controller, in light of the information provided in the collaboration agreement (for example point 2.2) noting that that study will also be carried out under the direction of the Co-Investigators.	IGARD members	Quorum of IGARD members	*"Please ensure that the 'territory of use' is changed in 2c to just "England and Wales", as on the updated application IGARD noted it still said "UK" and "England and Wales"*
NIC-15814-C6W9R	Monitor	26/03/2020	1. To provide evidence of an e-mail exchange (or similar) between NHS Improvement and NHS Digital confirming the agreement to disseminate data to NHS England as expressly permitted in terms of the mandatory request ("…such persons as may be agreed…").	IGARD members	Quorum of IGARD members	N/A
NIC-245768-V0N2T - Queen Mary University of London	Queen Mary University of London	12/03/2020	1. In respect of Barts Cancer Centre: a) To provide an analysis of whether Barts Cancer Centre should be considered as a joint Data Controller or Data Processor. b) To further explain the reference to Barts Cancer Centre under the QMUL data processor description.	IGARD members	Quorum of IGARD members	N/A

			2. To provide an explanatory narrative in section 1 and section 5 setting out why the other collaborator of the initial study is no longer involved.			
NIC-324040-N7L9R	Manchester University NHS Foundation Trust	05/03/2020	1. To provide confirmation that the funding for the study is provided exclusively by the NIHR.	IGARD members	Quorum of IGARD members	N/A
NIC-170100-T1Q8C	Cambridgeshire and Peterborough NHS Foundation Trust	19/03/2020	1. To provide a satisfactory justification for the disparity in size of the control group (25,000) versus the size of the cohort (c.1000). 2. To provide confirmation that ethics support is continuing for the major amendment outlined in the application, in increasing the cohort and control group from the initial size set out in the ethics approval (cohort 500=>1,000 and control 12,500 => 25,000). 3. To provide confirmation from HRA CAG that s251 support is continuing for the major amendment outlined in the application, in increasing the cohort and control group from the initial size as set out in the s251 support application (cohort 500=>1,000 and control 12,500 => 25,000).	IGARD Members	Quorum of IGARD members	*Condition two - met with caveat: in the circumstances, IGARD would be content to accept that they have given notice to the ethics committee and ask NHSD to insert a special condition to require the applicant to continue to use best endeavours to obtain confirmation, when the ethics committee resumes normal business after the COVID-19 pandemic abates and to provide an update on the status of these efforts no later than six months from the date of the DSA. If at any point the ethics committee declines to provide support for the amendment the applicant must notify NHSD immediately.* *Condition three - met with caveat: in the circumstances, IGARD would be content to accept that they have given notice to CAG and ask NHSD to insert a special condition to require the applicant to continue to use best endeavours to obtain confirmation, when CAG resumes normal business after the COVID-19 pandemic abates and to provide an update on the status of these efforts no later than six months from the date of the DSA.*

						If at any point CAG declines to provide support for the amendment the applicant must notify NHSD immediately. *Additionally, please add to Section 1 Abstract and include a note in CRM that this application returns to IGARD for any renewal, amendment etc, it is not suitable for precedent track and that the length of the DSA should be for no longer than a year.*

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 Oversight and Assurance Report.

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

- None notified to IGARD

Appendix B

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting,

21st April 2020, held via videoconference

In attendance (IGARD Members): Kirsty Irvine (Chair), Imran Khan, Geoffrey Schrecker.

In attendance (NHS Digital): Garry Coleman, Liz Gaffney, Frances Hancox, Dave Roberts, Eva Simmonds, Vicki Williams.

1	**Welcome** The IGARD Chair noted that this was a new weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD BAU meetings. IGARD members present would only be making comments and observations on any items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual DARS process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting would be received at the next Thursday meeting of IGARD and published as part of those minutes as an appendix. **Declaration of interests:** Geoff Schrecker noted a previous working relationship with some staff involved with NIC-240279 University of Oxford application when he was a member of the QResearch Advisory Board. It was agreed this did not represent a substantive conflict of interest.
2.1	<u>NIC-156334 University of Cambridge: INTERVAL and COMPARE trial cohorts: long term follow up of health outcomes and associations with genetic, biological and lifestyle traits</u> **Background**: This was an urgent amendment request in order support research relating to the COVID-19 pandemic to increase the data frequency from bi-annually to monthly; to permit the linkage of NHS Digital data to additional datasets to support COVID-19 research (Public Health England datasets, National Clinical Audits and other morbidity registers, and NHS provider organisations) and to permit visiting academics who are not employment by the University of Cambridge to access the data where valid visiting staff arrangements are in place with assurances from the individual's substantive employer. **IGARD Member Observations:** IGARD members noted that the application had last been reviewed by IGARD on the 21 June 2018 and had subsequently gone down NHS Digital's precedent route for extensions and renewals. IGARD members suggested that transparency materials should be updated for both the COMPARE and INTERVAL studies to both reflect the advice given by IGARD in 2018 and also be clear that the study had expanded to encompass COVID-19 related research. IGARD members suggested that a clear delineation be made within the application to be clear what is COVID-19 related work with a clear justification for the datasets requested, the data

	linkages and how the additional data, such as the NCRAS data would be relevant to COVID-19. IGARD members suggested Regulation 5 COPI approval as a minimum for the COMPARE cohort (because of the particular wording of the cohort's current consent materials which expressly noted that participants would be contacted about each new use of their data), but noted that best practice would be for both COMPARE and INTERVAL due to the extensive linkages taking place, which seem to go beyond the scope of the consent in the materials presented. NHS Digital and IGARD members discussed an appropriate exit or conversion strategy for the data which may need further development for both this and similar COVID-19 extensions to existing studies. IGARD members observed that any expansion to the original study would need to go through the relevant NHS Digital DARS process, ensuring there was a clear sunset clause for COVID-19 related data if not addressed elsewhere. IGARD members noted that ethics committees were expediating their processes and suggested that refreshed ethics would be required to acknowledge the substantive amendment; this would also support the Regulation 5 COPI route which would require up to date ethics approval. IGARD members advised they would wish to review this application again when it comes up for renewal, amendment or extension. IGARD members suggested this application would not be suitable for NHS Digital's precedent route. **Subsequent to the meeting:** IGARD members suggested that as an alternative to the COPI route, the applicant could consider uplifting their consent materials by communicating directly with cohort members about the new processing (for example by way of a mailout).
2.2	<u>GP Data for Planning & Research</u> **Background**: There is high demand for GP data in support of urgent care planning, audit and research directly related to COVID-19 and there is a burden on General Practice to ensure legitimate, controlled and proportionate data release. The British Medical Association (BMA) and Royal College of General Practitioners (RCGP) have requested a tactical solution to meet the demand and relieve the burden / responsibility. The GP Data for Planning and Research (GPDPR) principles have been agreed but in advance of that GPDPR dataset being launched, NHS Digital is responding to the request from the GP profession by proposing utilising the existing GPES system for a short-term emergency solution. **IGARD Observations:** IGARD members noted that there were three GP's on the current membership of seven, and that at Thursday meetings it could be arranged so that there would be at least one GP present for applications being presented under this temporary route. IGARD members noted the helpful briefing presented and that NHS Digital were still awaiting formal feedback from the National Data Guardian. In addition, IGARD noted NHS Digital would apply type 1 objections when collecting data but that work was ongoing with regard to national data opt outs for dissemination of data.

	IGARD members suggested that NHS Digital have a clear path for determining the legal basis for the dissemination of data, since some dissemination would be for direct care, and some in response to COVID-19 and under the COVID-19 Direction and Regulation 3 COPI but that for some applicants who wished to carry out more general COVID-19 research, not directly related to the national response, this would be covered under Regulation 5 COPI. IGARD members noted NHS Digital's robust procedure in place to ensure that GP Practices had appropriate transparency in place, working with colleagues from the BMA and RCGP to support relevant communications.
2.3	<u>NIC-240279 University of Oxford: D27 QResearch-Oxford Data Linkage Project</u> **Background**: This was an urgent request in order to support research relating to the COVID-19 pandemic. The request was already proceeding under NHS Digital's precedent 5 SIRO. The requested changes were to expand the GP practices contributing to include practices which use the SystemOne computer system; permission for QResearch to link NHS Digital data to an existing database of data from 185 intensive care units nationally usually known as the Intensive Care National Audit & Research Centre (ICNARC) database and COVID-19 testing database held by PHE; to add ICNARC as a joint Data Controller solely for COVID-19 research involving linked dataset with University of Oxford remaining sole Data Controller for all other QResearch purposes; to add permission for the University of Nottingham to act as Data Processor for COVID-19 research; and to increase the frequency from quarterly to monthly. **IGARD Observations:** IGARD members suggested that it be made explicitly clear that the data was pseudonymised at source and handled in a de-identified manner, and to remove any reference to anonymisation or the data being anonymous. IGARD members noted reference to tabulated data but suggested this be updated to be explicit this is aggregated with small numbers suppressed. IGARD members suggested that a clear delineation be made within the application to be clear what is COVID-19 related work (or that the application be split into two distinct Data Sharing Agreements). IGARD members advised they would wish to review this application again when it comes up for renewal, amendment or extension. IGARD members suggested this application would not be suitable for NHS Digital's precedent route.
2.4	<u>Clinical Trials update</u> Garry Coleman, Associate Director Data Dissemination, updated members present on the current clinical trials which were ongoing, as noted in both the UK Government's daily press updates and associated news items on the BBC news website, for instance the University of Oxford's Recovery Trial and NHS Blood & Transplant's convalescent plasma trial. IGARD suggested this be a standing item at Tuesday sessions.
2.5	<u>Trusted Research Environment (TRE)</u>

	Garry Coleman, Associate Director Data Dissemination, noted that the Scientific Advisory Group for Emergencies (SAGE) had stated that there should be a TRE in each of the four UK nations since legal bases varied across all four nations, and it was agreed that NHS Digital would be the TRE for England, which would include an analytical hub for analysis of data to be undertaken. IGARD noted the work undertaken by NHS Digital to progress this work at pace.
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.