Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 19th March 2020

In attendance (IGARD Members): Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Imran Khan, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Garry Coleman, Dave Cronin, Louise Dunn, Dickie Langley (Item 2.7), Karen Myers, Kimberley Watson, Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Anomika Bedi, Geoffrey Schrecker.

1	**Declaration of interests:** Nicola Fear noted a professional and personal link to the Cambridgeshire and Peterborough NHS Foundation Trust [NIC-170100-T1Q8C] application, it was therefore agreed that Nicola would be part of the discussion, however, would not contribute to the quorum of members making a recommendation for this application. **Review of previous minutes and actions:** The minutes of the 12th March 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 B).
2	**Data Applications**
2.1	University of Glasgow: HARMONY Outcome Trial GLP116174 - Electronic Health Records (EHR) ancillary sub-study (Presenter: Dave Cronin) NIC-213720-D5Z3L **Application:** This was a new application for identifiable Civil Registrations, Medical Research Information Service (MRIS) and Hospital Episode Statistics (HES) data. The purpose is for an ancillary study aiming to further the understanding of how EHR data can be organised into a queryable format to facilitate a more efficient, reliable, and cost-effective research process. The study forms part of the wider Harmony Outcome Trial which was a randomised, double blind, parallel-group, placebo-masked, controlled study to evaluate the effect of albiglutide on cardiovascular subcutaneously once weekly in a population of patients with Type 2 diabetes and a previous history of cardiovascular disease and who do not have optimal glycaemic control. NHS Digital advised IGARD that this application had been submitted for advice on 1) the proposed Data Controllership; 2) the suggested benefits to the health and social care system in accordance with the relevant NHS Digital published Standard as underpinned by the Health and Social Care Act 2012; 3) any other aspect of the application. **Discussion:** IGARD welcomed the application which came for advice on the Data Controllership and the benefits outlined for the Health and Social Care and without prejudice to any additional issues that may arise when the application is fully reviewed. In respect of Data Controllership, NHS Digital advised IGARD that the applicant had confirmed that GlaxoSmithKline UK Limited (GSK) and the University of Glasgow were considered joint Data Controllers; and that Duke University based in the USA was not considered a Data Controller but viewed more in terms of a “customer”. IGARD queried why Duke University could not also be considered a Data Controller, noting their role with the study and were advised by NHS Digital that they had explored this option but to be considered and named as

	a Data Controller, Duke University would have to sign a Data Sharing Framework Contract with NHS Digital, which had not been undertaken and that this was complex with them being a USA company since they would have to comply with security requirements to be part of the Data Sharing Agreement. In-light of the evidence provided, IGARD agreed with NHS Digital that the Data Controllership arrangements would present challenges in respect of contracting with entities outside the UK/EU. In respect of the benefits outlined for Health and Social Care, NHS Digital had an obligation to disseminate data in line with the provisions of both the Health & Social Care Act 2012 and The Care Act 2014, which required the establishment of benefits to the health and social care. It was noted that the methodology outlined in this application was well established in the UK and the application did not provide anything novel or new. NHS Digital also noted that the application had not been updated in line with published Standards and IGARD endorsed this point. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** IGARD welcomed the application which came for advice, particularly on data controllership and the benefits outlined for health and social care in England and Wales (and without prejudice to any additional issues that may arise when the application is fully reviewed). IGARD agreed with NHS Digital that the Data Controllership arrangements would present challenges in respect of contracting with entities outside the UK/EU. Regarding benefits to health and social care, IGARD observed that - based on their understanding of the study and the evidence presented - there did not appear to be anything methodologically unique and could not see how the research would add to the well-established evidence base that already proves the utility of using this type of data.
2.2	<u>University of Leeds: MR1172 - CE-MARC - Clinical Evaluation of Magnetic Resonance imaging in Coronary Heart Disease (Presenter: Louise Dunn) NIC-147908-CPCPG</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) data for the purpose of a obtaining long-term mortality data for a study looking to establish the diagnostic accuracy of a cardiovascular magnetic resonance (CMR) protocol with x-ray coronary angiography as the reference standard; and to compare CMR with single-photon emission computed tomography (SPECT), in patients with suspected Coronary Heart Disease (CHD). NHS Digital advised (as outlined in section 1 (Abstract)) that a previous iteration of this application had been reviewed by IGARD's predecessor the Data Access Advisory Group (DAAG) on the 17th February 2015, where DAAG had been unable to recommend for approval as there were concerns that the consent materials did not provide an adequate legal basis for the disclosure of the data. NHS Digital advised that following this review, the data had been disseminated under SIRO / Director approval. **Discussion:** IGARD welcomed the application and noted the importance of the study; and noted the historical information of the application outlined by NHS Digital and in section 1 of the application. IGARD had a discussion with regard the previous review undertaken by its predecessor the Data Access & Advisory Group (DAAG) on the 17th February 2015 and it was IGARD's view that DAAG's view on the application and the issues with the consent materials were correct and endorsed by this Group. IGARD noted that within supporting document 3, the ethics approval confirmation letter, there was a referral to an 'attached document' that outlined the condition of approval and advised

	NHS Digital that this had not been provided. IGARD therefore asked that written confirmation was provided confirming that the ethics approval conditions had been met. IGARD queried the point raised by DAAG previously on any potential involvement of any commercial organisations; and were advised by NHS Digital that there was no current evidence of any commercial involvement. IGARD noted the update from NHS Digital and asked that a special condition was inserted in section 6 (Special Conditions) expressly stating that no commercial use of the data was permitted. IGARD queried if the data already held by the University of Leeds could be pseudonymised by destroying the identifiers already held by the applicant; NHS Digital advised that this may be possible, however NHS Digital would need to have further discussions with the applicant to clarify this. IGARD suggested that if it was **not** possible to pseudonymise the data held by the applicant, that NHS Digital carried out a List Clean of the cohort. The applicant should communicate with the surviving cohort members and provide a revised Privacy Notice along with a brief update on the study and current outputs and provide any other clarification necessary, as identified in the 2015 DAAG review of the consent materials. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and that the applicant should work with NHS Digital on a Privacy Notice that was compliant with the General Data Protection Regulation (GDPR). **Outcome Summary:** Recommendation to defer, pending: 1. To provide written confirmation that the ethics approval conditions (referred to as a separate document in the ethical approval) have been met. 2. To insert a special condition in section 6 expressly stating that no commercial use of the data is permitted. 3. To advise if it is possible to pseudonymise the data held by the applicant (and that the applicant will then destroy any identifiers that they currently hold). 4. If it is not possible to pseudonymise the data held by the applicant, IGARD recommend that NHS Digital carries out a List Clean of the cohort and that the applicant should communicate with the surviving cohort members and provide a revised Privacy Notice along with a brief update on the study and current outputs and provide any other clarification necessary, as identified in the 2015 DAAG review of the consent. 5. The applicant should work with NHS Digital on a Privacy Notice that is GDPR compliant. The following advice was given: 1. IGARD noted the importance of the research / study undertaken and the need for the applicant to continue to hold data. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, and in light of this it was suggested that NHS Digital might wish to consider a short term extension to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD. 2. IGARD suggested the applicant may wish to apply for a List Clean in order to provide an updated Privacy Notice to the participants, in the event it was not possible to pseudonymise the data held by the applicant.
2.3	<u>Royal College of Psychiatrists: National Clinical Audit of Psychosis (Presenter: Louise Dunn) NIC-209200-S9H5R</u> **Application:** This was a new application for pseudonymised Mental Health Services Data Set (MHSDS). The National Clinical Audit of Psychosis (NCAP) is commissioned by the

	Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England as part of the Clinical Audit and Patient Outcomes Programme. The audit aims to provide those who commission, deliver and use services for people with psychosis with high quality data on the process and outcomes of NHS care. The purpose of the application is to carry out a feasibility study into the use of routine data for the audit in the future. NHS Digital advised IGARD that this application was the first of its kind to be submitted for review for an HQIP audit which also includes both HQIP and NHS England as joint Data Controllers. **Discussion:** IGARD noted the update from NHS Digital in relation to this application being the first of its type, with both HQIP and NHS England as joint Data controllers; and advised that further discussions were required to agree how to manage these applications going forward, where there would be an amendment to **only** add NHS England as a joint Data Controller. IGARD noted and endorsed NHS Digital's review that the Data Controllers did **not** meet NHS Digital's Standard for privacy notices. IGARD asked that NHS Digital satisfy itself and provide written confirmation to IGARD that both Data Controllers, the Healthcare Quality Improvement Partnership (HQIP) and NHS England had published revised Privacy Notices, ensuring that they were compliant with the notice requirements under the General Data Protection Regulation (GDPR) and met NHS Digital's published 10a Transparency Standard, and before data could flow. IGARD queried the reference in section 5(a) (Objective for Processing) to maternity-related data, and noted this did not appear to tie in with the information outlined in the rest of the application and asked that written confirmation was provided confirming that NHS Digital was not flowing maternity-related data. In addition, IGARD noted that some of the information in section 5(a) was repeated and asked that this was amended to remove any repetition of information. IGARD also noted that some of the acronyms within section 5(a) of the application were not always defined upon first use and asked that this was updated as necessary and to ensure they were spelt out upon first use to make this clear. IGARD queried the reference in section 5(a) that the age range of the cohort was 14-65 years and asked that confirmation was provided that this was correct; and if this was correct, that further confirmation was outlined of how the additional protection owed to young people under the GDPR had been addressed. IGARD noted that HQIP's Article 9 GDPR legal basis outlined in section 1 (Abstract) did not address the requirements of paragraph 3 of Article 9 and asked that this was updated with further details. IGARD queried the reference to *"package 1d"* within the data minimisation column in section 3(b) (Additional Data Access Requested) and section 5(a); and asked that a further explanation was provided of what this comprises. IGARD noted that section 3b and section 5(a) did not specifically reference the size of the cohort and asked that this was updated to reflect this information. **Outcome:** recommendation to approve subject to the following conditions: 1. NHS Digital to satisfy itself and provide written confirmation to IGARD that both Data Controllers have published revised Privacy Notices, ensuring that they are compliant with the notice requirements under the GDPR and which meets NHS Digital's published 10a Transparency Standard.

	2. To provide written confirmation that NHS Digital is not flowing any maternity-related data. The following amendments were requested: 1. To update section 1 with further details of how HQIP is addressing the requirements of paragraph 3 Article 9 GDPR. 2. To amend section 3(b) and section 5(a) to provide a further explanation of "package 1d" and what this comprises. 3. To update section 3(b) and section 5(a) to specifically reference the size of the cohort. 4. To amend section 5(a) to remove any repetition of information. 5. To amend section 5(a) to ensure that all acronyms upon first use be defined and further explained, as may be necessary for a lay reader. 6. To provide confirmation that the age range of the cohort is 14-65 years; and to confirm how the additional protection owed to young people under GDPR has been addressed. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.4	<u>Cambridgeshire and Peterborough NHS Foundation Trust: Improving diagnosis and management in dementia with Lewy bodies using the CPFT Research Database (CRATE). (Presenter: Stuart Blake) NIC-170100-T1Q8C</u> **Application:** This was a new application for identifiable Hospital Episodes Statistics (HES) and pseudonymised Civil Registrations data. The purpose is for a project that will identify a cohort with Lewy bodies (DLB) cases and non-DLB disease dementia controls, to allow a detailed examination of their characteristics and outcomes. The Research Team will examine the patterns of early predictors, presentations and symptoms associated with DLB to facilitate early diagnosis. This will inform the development and testing of a natural language processing (NLP) app to aid diagnostic decision making for clinicians in real time. **Discussion:** NHS Digital advised IGARD why Cambridgeshire and Peterborough NHS Foundation Trust were considered the sole Data Controller and IGARD confirmed they were satisfied with this explanation, including that those involved with the project had honorary contracts in place. IGARD noted and endorsed NHS Digital's review that the applicant **did** meet NHS Digital's Standard for privacy notices and in addition provided positive feedback on the Privacy Notice. IGARD noted the information outlined within the application on the non-DLB control group of 25,000 and the cohort of 1,000 and asked that a satisfactory justification was provided for the disparity in size of the control group, since IGARD noted that best practice was to have a control group no bigger than 5x since it was not increasing the statistical power of the analysis IGARD noted that the original ethics approval was based on an initial size cohort size of 500 and control group of 12,500 and asked that confirmation was provided that ethics approval was continuing for the major amendment outlined in the application, in increasing the cohort and control group to 1,000 and 25,000 respectively. In addition, to ensure that the cohort and control group size was accurately reflected throughout the application, for example amending reference to 250,000. In addition, IGARD also asked that confirmation was provided from the Health Research Authority Confidentiality Advisory Group (HRA CAG) that s251 support was continuing for the major amendment outlined, which was to increase the cohort from 500 to 1,000, and the control group from 12,500 to 25,000.

	IGARD queried the benefits and outputs outlined in section 5 (Purpose / Methods / Outputs), specifically the language when describing these, for example *"we will"*; and asked that this was revised to ensure the benefits and outputs were both realistic and achievable. IGARD noted the reference in section 1 (Abstract) and section 5 to *"natural language processing"* and asked that this was updated with a further explanation of this term. IGARD queried the reference in section 5(c) (Specific Outputs Expected) to *"unstructured text"* and asked that a further explanation was provided of the meaning of this. In addition, NHS Digital advised IGARD that they do not share 'free text' as part of any NHS Digital datasets. IGARD noted the information provided in section 5(b), specifically the paragraph that started "*Analyses will be completed in line with the stated research aims…"* and asked that this was updated to make it clearer with a brief lay summary at the start of this paragraph. IGARD queried the statement in section 5(d) (Benefits) to *"All aspects of this project have the potential to make a positive impact on patient care and DLB research within a short time."* and asked that a further explanation was provided on what was meant by *"short time".* IGARD noted that the DPA Registration expiry dates in section 1(b) (Data Controllers) had expired and asked that these were updated to reflect the correct dates. **Outcome Summary:** recommendation to approve subject to the following conditions: 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). The following amendments were requested: 1. To revise the language in section 5 when describing the potential benefits and outputs and to ensure that these are realistic and achievable. 2. To update section 1 and section 5 with a further explanation of the term *"natural language processing"*. 3. To provide a further explanation in section 5(c) of what is meant by *"unstructured text"*. 4. To update section 1(b) to ensure this reflects the correct DPA Registration expiry dates. 5. To update section 5(b) to include a brief lay summary at the start of the paragraph *"Analyses will be completed in line with the stated research aims…"*. 6. To provide a further explanation in section 5(d) to explain what is meant by *"short time"*. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
2.5	<u>Department of Health and Social Care: Access to Pseudonymised datasets through the NHS Digital Portal (Presenters: Kimberley Watson / Garry Coleman) NIC-365132-V5S8H</u> **Application:** This was a new application for pseudonymised Hospital Episodes Statistics (HES), Mental Health Services Data Set (MHSDS) and Maternity Services Data Set (MSDS). The NHS Digital Portal / Data Access Environment (DAE) enables organisations to access data for a wide range of data analytical purposes. The system is an online analytical

	processing tool through which the users of this organisation data has access to a wide range of analytical, graphical, statistical and reporting functions. The applicant will use the NHS Digital Portal / DAE through the analysis of data as listed in this Data Sharing Agreement (DSA), in support of the Secretary of State for Health in delivery of their duties set out within the National Health Service Act 2006. **Discussion:** IGARD noted that some of the acronyms within section 5 (Purpose / Methods / Outputs) of the application were not always defined upon first use and asked that this was updated as necessary and to ensure they were spelt out upon first use to make this clear. IGARD queried the information outlined in section 5(b) (Processing Activities), specifically who would be accessing the NHS Digital data, noting reference to analysts, officials etc, and were asked that it was made explicitly clear that **only** Analysts permitted to hold a licence would have access to the data supplied under this Data Sharing Agreement (DSA); and that any other *"users"* or *"officials"* would only be in receipt of the outputs produced by the Analyst(s). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions) expressly stating that upon renewal / amendment of this application, the applicant should have published a Privacy Notice that was compliant with the notice requirements under the General Data Protection Regulation (GDPR). IGARD also advised the upon renewal IGARD would expect to see an updated GDPR compliant Privacy Notice. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve 1. To update section 5 to ensure acronyms are spelt out on first use. 2. To update section 5(b) to make it explicitly clear that only Analysts permitted to hold a licence will have access to the data supplied under this Data Sharing Agreement; and that any other "users" or "officials" will be in receipt of the outputs produced by the Analyst(s). 3. To insert a special condition in section 6 expressly stating that upon renewal / amendment of this application, the applicant should have published a Privacy Notice that is compliant with the notice requirements under the GDPR. The following advice was given: 1. IGARD advised the upon renewal IGARD would expect to see an updated GDPR compliant Privacy Notice. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.6	<u>Department of Health and Social Care: Access to pseudonymised SUS PbR datasets (Presenter: Kimberley Watson / Garry Coleman) NIC-365145-G2P9F</u> **Application:** This was a new application for pseudonymised Secondary Uses Service (SUS) Payment By Results (PbR) data. The applicant will use the datasets through the analysis of data as listed in this Data Sharing Agreement (DSA), in support of the Secretary of State for Health in delivery of their duties set out within the National Health Service Act 2006. Analysts and officials will use data accessed via this DSA to explore and analyse these detailed datasets to provide insights that will inform policy decisions. They will also use the data and evidence to respond rapidly to emergent challenges and issues, for example analysing in

	detail the impact on services from any pandemic contagious illnesses; providing actionable evidence and briefing to decision makers. **Discussion:** IGARD noted that some of the acronyms within section 5 (Purpose / Methods / Outputs) of the application were not always defined upon first use and asked that this was updated as necessary and to ensure they were spelt out upon first use to make this clear. IGARD queried the information outlined in section 5(b) (Processing Activities), specifically who would be accessing the NHS Digital data, noting reference to analysts, officials etc, and were asked that it was made explicitly clear that **only** Analysts permitted to hold a licence would have access to the data supplied under this Data Sharing Agreement (DSA); and that any other *"users"* or *"officials"* would only be in receipt of the outputs produced by the Analyst(s). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. In addition, IGARD asked that a special condition was inserted in section 6 (Special Conditions) expressly stating that upon renewal / amendment of this application, the applicant should have published a Privacy Notice that was compliant with the notice requirements under the General Data Protection Regulation (GDPR). IGARD also advised the upon renewal IGARD would expect to see an updated GDPR compliant Privacy Notice. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. **Outcome Summary:** recommendation to approve 1. To update section 5 to ensure acronyms are spelt out on first use. 2. To update section 5(b) to make it explicitly clear that only Analysts permitted to hold a licence will have access to the data supplied under this Data Sharing Agreement; and that any other "users" or "officials" will be in receipt of the outputs produced by the Analyst(s). 3. To insert a special condition in section 6 expressly stating that upon renewal / amendment of this application, the applicant should have published a Privacy Notice that is compliant with the notice requirements under the GDPR. The following advice was given: 1. IGARD advised the upon renewal IGARD would expect to see an updated GDPR compliant Privacy Notice. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.7	<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'; and to allow 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.

	The application was been previously considered on the 6th February 2020 when IGARD had been unable to recommend for approval as the relevant documents, essential for IGARD's review, were not available; and at the request of IGARD was withdrawn from the meeting on the 27th February 2020 due to the minutes from the 6th February 2020 not yet being published. **Discussion:** IGARD noted the efforts in addressing the queries raised at the IGARD meeting on the 6th February 2020, however IGARD noted that they still did not feel sufficient evidence had been provided in order to see how CPRD judged that the data to be anonymous. IGARD noted that the Information Commissioner's Office (ICO) guidance was still under review and in light of the uncertainty and in the absence of guidance or case law to establish if the data was truly anonymised in the new legislative framework that there were two possible outcomes for NHS Digital to consider. IGARD advised that on the evidence available they were not in a position to provide an opinion on whether in all cases the data released under sublicence by CPRD was "anonymous" (and outside of the scope of the General Data Protection Regulation (GDPR)). This caveat was made in light of the absence of any current guidance in this space which addresses the changes introduced by GDPR / Data Protection Act (DPA) 2018, and in light of the ICO guidance on this topic being currently under review. IGARD noted that if the data **was anonymous** and therefore outside the scope of the GDPR, that a special condition was inserted in section 6 (Special Conditions) expressly stating that in the interests of transparency the applicant should keep a log of how they have assured themselves that **in each instance** a sub-licencee is receiving data that has been sufficiently anonymised to render it truly "anonymous" and outside GDPR. In addition, IGARD asked that this log may be audited by NHS Digital. IGARD also asked that a special condition was inserted in section 6 expressly stating that the applicant must produce a process flow diagram and checklist, that provided evidence of how the intended benefits (and accrued benefits at time of a sub-licencee's application to CPRD for extension or renewal) to the Health or Social Care in England and Wales would be established and recorded for each sub-licence agreement, specifically a draft process with NHS Digital within 1 month of agreement signature; and a process agreed with NHS Digital within 3 months of agreement signature IGARD asked that a special condition was inserted in section 6 stating that details of the record of intended benefits (and accrued benefits at time of a sub-licensee's application to CPRD for extension or renewal) would be included in the flow of sub-licensing information provided by the applicant to NHS Digital on a regular basis, specifically intended benefits to continue to be captured as presently; noting that a system change may be required, CPRD to confirm by time of agreement renewal (Oct 2020) the implementation timetable for the system change to enact that flow of data; and to demonstrate when requested (with suitable notice) to a senior NHS Digital's Data Access Request Service (DARS) member of staff how the benefits are being captured and assessed through the end to end CPRD process. IGARD noted that if the data **was not anonymous** and therefore within the scope of GDPR, that the application was revised throughout to reflect that it was personal information under GDPR and that numerous amendments would need to be made to the application and any supporting documentation, particularly in respect of sub-licencees outside the UK. IGARD asked that a special condition was inserted in section 6 expressly stating that the applicant must produce a process flow diagram and checklist, that provided evidence of how the intended benefits (and accrued benefits at time of a sub-licencee's application to CPRD for extension or renewal) to the Health or Social Care in England and Wales would be established and recorded for each sub-licence agreement, specifically a draft process with NHS Digital

	within 1 month of agreement signature; and a process agreed with NHS Digital within 3 months of agreement signature IGARD asked that a special condition was inserted in section 6 stating that details of the record of intended benefits (and accrued benefits at time of a sub-licensee's application to CPRD for extension or renewal) would be included in the flow of sub-licensing information provided by the applicant to NHS Digital on a regular basis, specifically intended benefits to continue to be captured as presently; noting that a system change may be required, CPRD to confirm by time of agreement renewal (Oct 2020) the implementation timetable for the system change to enact that flow of data; and to demonstrate when requested (with suitable notice) to a senior NHS Digital DARS member of staff how the benefits are being captured and assessed through the end to end CPRD process. IGARD advised that they would be requesting that NHS Digital provide regular updates on the sub-licencing arrangements and details on how the checklist was working in practice to ensure that each sub-licencee was establishing the benefit to health and social care in England and Wales and that this was being documented. **Outcome Summary:** If the data **is anonymous** and therefore outside the scope of GDPR, IGARD recommend for approval subject to the following conditions: 1. To insert a special condition in section 6 expressly stating that in the interests of transparency the applicant should keep a log of how they have assured themselves that **in each instance** a sub-licencee is receiving data that has been sufficiently anonymised to render it truly "anonymous" and outside GDPR. This log may be audited by NHS Digital. 2. To insert a special condition in section 6 expressly stating that the applicant must produce a process flow diagram and checklist, that provides evidence of how the intended benefits (and accrued benefits at time of a sub-licencee's application to CPRD for extension or renewal) to the Health or Social Care in England and Wales will be established and recorded for each sub-licence agreement, specifically: a) Draft process with NHS Digital within 1 month of agreement signature b) Process agreed with NHS Digital within 3 months of agreement signature 3. To insert a special condition is section 6 stating that Details of the record of intended benefits (and accrued benefits at time of a sub-licensee's application to CPRD) for extension or renewal) will be included in the flow of sub-licensing information provided by the applicant to NHS Digital on a regular basis, specifically: a) Intended benefits to continue to be captured as presently. b) Noting that a system change may be required, CPRD to confirm by time of agreement renewal (Oct 2020) the implementation timetable for the system change to enact that flow of data. c) To demonstrate when requested (with suitable notice) to a senior NHS Digital DARS member of staff how the benefits are being captured and assessed through the end to end CPRD process. **Outcome Summary:** If the data **is not anonymous** and therefore within the scope of GDPR, IGARD recommend for approval subject to the following conditions: 1. To revise the application throughout to reflect that it is personal information under GDPR and that numerous amendments would need to be made to the application and any supporting documentation, particularly in respect of sub-licencees outside the UK. 2. To insert a special condition in section 6 expressly stating that the applicant must produce a process flow diagram and checklist, that provides evidence of how the

	intended benefits (and accrued benefits at time of a sub-licencee's application to CPRD for extension or renewal) to the Health or Social Care in England and Wales will be established and recorded for each sub-licence agreement, specifically: a) Draft process with NHS Digital within 1 month of agreement signature b) Process agreed with NHS Digital within 3 months of agreement signature 3. To insert a special condition is section 6 stating that details of the record of intended benefits (and accrued benefits at time of a sub-licensee's application to CPRD) for extension or renewal) will be included in the flow of sub-licensing information provided by the applicant to NHS Digital on a regular basis, specifically: a) Intended benefits to continue to be captured as presently. b) Noting that a system change may be required, CPRD to confirm by time of agreement renewal (Oct 2020) the implementation timetable for the system change to enact that flow of data. c) To demonstrate when requested (with suitable notice) to a senior NHS Digital DARS member of staff how the benefits are being captured and assessed through the end to end CPRD process. The following advice was given: 1) IGARD advised that on the evidence available they are not in a position to provide an opinion on whether in all cases the data released under sublicence by CPRD is "anonymous" (and outside of the scope of GDPR). This caveat is made in light of the absence of any current guidance in this space which addresses the changes introduced by GDPR / DPA 2018, and noting that the ICO guidance on this topic is currently under review. 2) IGARD advised that they would be requesting that NHS Digital provide regular updates on the sub-licencing arrangements and details on how the checklist is working in practice to ensure that each sub-licencee is establishing the benefit to health and social care in England and Wales and that this is being documented. It was agreed the conditions would be approved Out of Committee (OOC) by IGARD members.
3	<u>Returning Applications</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. • NIC-148130-46N08 University of Oxford • NIC-164594-K4C5N University College London • NIC-204535-L4S1P NHS England • NIC-94749-Y1R8N University of Sheffield IGARD welcomed the four applications 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 and Assurance Report which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.
4	<u>Randomised Evaluation of Covid-19 Therapy (Recovery): Protocol and Patient Information Sheet (Reviewed by IGARD Out of Committee (OOC))</u> **Protocol:** There are currently no approved treatments for Covid-19, a disease induced by the novel coronavirus SARS-CoV-2 that emerged in late 2019. The UK New and Emerging

	Respiratory Virus Threats Advisory Group (NERVTAG) advised that several possible treatments should be evaluated, including Lopinavir-Ritonavir, Interferon β, and low-dose corticosteroids. These groups also advised that other treatments will soon emerge that require evaluation. A World Health Organization (WHO) expert group issued broadly similar advice. The protocol describes a randomised trial among adults hospitalised for confirmed COVID-19. **Outcome:** IGARD confirmed they were supportive of this vital piece of work and provided initial comments in a short time frame on the consent materials, without prejudice to any further comments that may arise in the context of a live (DARS) application.
5 **5.1**	AOB: <u>Sarah Baalham</u> Both IGARD and NHS Digital noted that the meeting on the 12th March 2020 was Sarah Baalham's final meeting and wished to extend their sincere thanks for her significant contribution over the last three years during her tenure on IGARD. 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 13/03/20

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)

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