Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 6 August 2020

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Lay Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS) (Observer: item 2.4)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Richard Hatton	Clinical Informatics (Observer: items 2.1 to 2.4)
Beth Simpson	Data Access Request Service (DARS) (Observer: 2.1 to 2.4)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. Nicola Fear noted a personal and professional link to the Head of the Centre for Longitudinal Studies (CLS) unit at University College London (NIC-49297-Q7G1Q UCL, NIC-51342-V1M5W UCL, NIC-49826-T0J7C UCL) but noted no specific connection with the application or staff involved. It was agreed that this was not a conflict of interest and Nicola would remain as an observer for these three applications but would not form part of the recommendation making. In addition when NIC-49297-Q7G1Q was discussed at IGARD on the 20th July 2017,

	Nicola Fear did not note the personal and professional link to the Head of the CLS unit at UCL, it was agreed for the application at the time, that this was not a conflict of interest. Maurice Smith noted professional links to AIMES Management Service (NIC-374223-P4P4L National Institute for Health Research (NIHR)) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Paul Affleck noted professional links to AIMES Management Service (NIC-374223-P4P4L National Institute for Health Research (NIHR)) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. **Review of previous minutes and actions:** The minutes of the 30th July 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	<u>NHS England (SKH): GDPPR COVID-19 – NHS England - Pseudo (Presenter: Garry Coleman / Duncan Easton) NIC-384608-C9B4L</u> **Background:** This was a new application for GPES Data for Pandemic Planning and Research (GDPPR) data. COVID-19 has led to a change in demand on general practices (GPs), including an increasing number of requests to provide patient data to inform planning and support vital insights on the cause, effects, treatments and outcomes for patients of the virus. To support the response to the COVID-19 outbreak, NHS Digital has been legally directed to collect and analyse healthcare information about patients, including from their GP record, for the duration of the COVID-19 emergency period, under the COVID-19 Public Health Directions 2020 (COVID-19 Direction). All GP practices in England are legally required to share data with NHS Digital for this purpose under the Health and Social Care Act 2012. This collection will reduce burden on general practices, allowing them to focus on patient care and support the COVID-19 response. The application had been previously considered on the 23rd July 2020 when IGARD had deferred making a recommendation pending: IGARD endorsed the comments made by PAG and in reference to the two specific requests from PAG, suggested that a) NHS Digital may wish to consider auditing this organisation in relation to this application / data sharing agreement, b) NHS Digital to provide confirmation whether or not the applicant could access the NHS Digital data in an NHS Digital TRE; and if not, why not; To update section 3 to address the Common Law Duty of Confidentiality, with the application of National Data Opt Out in regards to the use of a statutory exemption versus the nature of the data as pseudonymised data and to make this consistent; IGARD suggested that NHS England update their privacy notice to reflect this new dataset and to ensure compliance with the NHS Digital Standard; To update section 5(a) and section 5(b) to provide justification for the data requested, and any onward dissemination of the data; To amend section 5(a) to state *"…cases of the data include **and** are limited to the COPI Regulations";* To provide further clarification in section 5(a) of how the provision of the GDPPR data will meet the objectives; To clarify within the application as to whether the GDPPR data will be linked, explain the purpose for this and provide details of the process of linkage; To provide clarification in section 5(a), clearly distinguishing between Risk Stratification for the purpose of modelling and planning, and the purpose of identification of individuals for individual intervention; IGARD suggested that the applicant provide further information in section 5(c) and section 5(d) of the target dates for this

	urgent dissemination of data; To insert a special condition in section 6 that any further dissemination of the GDPPR data under this DSA should be subject to oversight from a group represented by the GP profession and patients/Lay members; To provide further clarity on the use of COPI Regulations for the use of pseudonymised data and to consider whether REC approval should be sought; To provide justification as to whether sub-licensing is the appropriate route for this application or whether other options, including (but not limited to) adding as joint Data Controller(s) and / or Data Processor(s); or other organisations applying directly to NHS Digital; To confirm if any commercial organisations are involved in sub-licensing and if so, confirmation that the application will come through NHS Digital for an amendment; To confirm that if a sub-licensing model is used, NHS Digital will maintain a public and transparent register of all such sub-licenses together with details of data disseminated; IGARD suggested If there are any substantial amendments to this application, this should go via PAG prior to being reviewed by IGARD; Accepting the large number of processing and storage locations listed, any additional locations, would constitute an amendment, and as such would not be suitable for NHS Digital's Precedent route or Director / IAO approval; IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment; IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st July and 4th August 2020. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 22nd July 2020, (notes from that meeting had been attached to the IGARD minutes from the 23rd July 2020), and on the 5th August 2020 (see Appendix B). IGARD noted that the application had been extensively re-written since the last review. IGARD noted and supported the comments made by PAG from the 5th August 2020, and with reference to point 1 "*In order to satisfy ourselves that all alternative avenues (to large data transfers) have been fully explored, PAG respectfully request that NHS Digital to provide documentary evidence of the discussion with each of the available Trusted Research Environments (including NHS Digital's TRE and the TRE already established by NHS England OpenSAFELY) establishing that these TREs would be unable to satisfy the needs of NHS England in regard its responsibilities around research and planning as applicable to the COVID-19 pandemic…*" and requested that relevant written documentary evidence be provided and uploaded to NHS Digital's Customer Relationship Management (CRM) system with regard to the full exploration of TREs. IGARD noted and supported the comments made by PAG from the 5th August 2020, and with reference to point 5 "*PAG requested that the statement within section 3c be amended to make clear that Type 1 opt-outs would be upheld in relation to GP data*" and requested that a statement be inserted into section 3(c) (Patient Objections) to clarify that the type 1 opt-outs would be upheld in relation to GP data. IGARD noted and supported the comments made by PAG from the 5th August 2020, and with reference to point 6 "*PAG also requested that on page 21 it was made explicit that PHE will not have access to the GP data. Also that it is explicitly that the approval route for GP linkage was through NHS England's approval team to ensure that COPI was appropriately applied and related to data provided by NHS Digital*" and suggested that section 5 (Purpose / Methods / Outputs) be updated to be clear that Public Health England (PHE) would not have access to the data, that it be explicitly clear that the approval route for GP linkage was through NHS

	England's approval team and in addition to clearly explain **what** the NHS England approval process was, for transparency. IGARD noted and supported the comments made by PAG from the 5th August 2020, and with reference to point 8 "*PAG advised that the scale and nature of this new processing activity warrants open publication of any updated Data Protection Impact Assessment*". IGARD agreed that an appropriate DPIA should be produced and noted the special condition which had been inserted in section 6 (Special Conditions) "*The DPIA for NHS COVID-19 datastore and datastore (sic) must be updated to mention this dataset within 6 weeks of receiving the data*". IGARD noted the comment made by PAG from the 5th August 2020, and with reference to point 3 "*The PAG expects that whichever route is taken, there will continue to be full and proper engagement with the profession via JGPITC and GP data controllers, proper safeguards on access to data, whether that be in NHSE or a TRE, and that all IG and legal issues are satisfactorily addressed, as was the case with the GPES process and the GP Data for Research and Planning programme",* IGARD additionally suggested that any engagement with the GP Data Controllers in the future, should be done through the appropriate avenues. IGARD noted the comment made by PAG from the 5th August 2020, and with reference to point 7 "*PAG wished to advise IGARD that we feel that as a general position, any and all derived intellectual property (such as machine learning models, AI, and algorithms, etc) from the GP data must remain the property of the NHS (and ideally open-sourced or otherwise published for maximum public and professional benefit). This clause should cascade down through any processing arrangements*." IGARD suggested that this point be explored further by NHS Digital with the appropriate stakeholders. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that an additional special condition be inserted in section 6 that that the applicant should update and publish a General Data Protection Regulation (GDPR) compliant Privacy Notice, as assessed by NHS Digital and within 6 weeks of receiving the data, aligning that timing with the publication of the DPIA special condition. IGARD suggested rewording the special condition in section 6 as follows to make it clear that both GDPR applies and also that even though the data is pseudonymised it is being handled as confidential patient information under COPI: *"The Disseminated data, provided by NHS Digital to the Data Controllers, is pseudonymised patient information and is treated as confidential patient information under COPI. The Disseminated data must be protected by the Data Controller and its Data Processors in accordance with the GDPR and COPI. In particular, the Data Controller must ensure that it and its Data Processors comply with the Data Controller's legal responsibilities under COPI when processing the Disseminated data, including the restrictions laid down in Regulation 7 of COPI."* IGARD suggested that section 5(c) (Specific Outputs Expected, including Target Date) be updated to remove the text "…*as well as diagnoses recorded*" since it was not felt relevant to this application. IGARD noted a number of acronyms were noted in section 1 (Abstract) and section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example "ExCo", "TDA", "nosocomial". Noting the sentence in section 5(b) (Processing Activities) "*The COVID Data Store consists of different areas of processing, one of those is the Palantir Foundry Platform. The GDPR data will not be processed by Palantir or ingested into the Foundry Platform*", suggested it be

	explicitly clear that the Palantir Foundry Platform were not involved with the dataset, storage or other form of processing under this application or Data Sharing Agreement (DSA). IGARD noted a number of benefits had been outlined in section 5(d) (Benefits) but suggested that these be refined and updated to ensure they were both realistic and achievable within the timeframe of the DSA and data disseminated under this application. Noting that everyone has an ethnicity, suggested that where the term "*ethnic*" was used, it was prefaced with "*minority*". IGARD noted in section 5(a) (Objective for Processing) reference to "*Use Case 04 – mortality increased risk in patients with obesity*" and asked if this also included those considered to be 'overweight' and if so, to update the text in section 5 appropriately. IGARD noted in section 5(a) reference to "*Use Case 05 – vaccinations and immunisations*" however it was unclear as whether this workstream would also include school vaccinations and suggested section 5 be updated to clarify. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's precedent route. **Outcome:** recommendation to approve. The following amendments were requested: 1. IGARD noted the comments made by PAG: a. With reference to point 1, to provide relevant documentary evidence and upload to CRM. b. With reference to point 5, to amend the statement in 3(c) to clarify that type 1 opt-outs would be upheld in relation to GP data. c. With reference to point 6, that section 5 be updated as suggested, but in addition requested that it be clearly explained **what** the NHS England approval process was. d. With reference to point 8, agreed that an appropriate DPIA should be produced (noting the special condition in Section 6). 2. To amend the special condition in section 6 stating that within 6 weeks a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published 3. To update the special condition in section 6 with regard to GDPR and CPI. 4. To update section 5(c) to remove reference to '*diagnoses recorded'*. 5. To amend section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader. 6. To make it explicitly clear in section 5 that Palantir Foundry Platform are **not** involved with the dataset, storage or other form of processing under this application. 7. To revise the language in section 5(d) and ensure that the benefits are realistic and achievable. 8. Preface 'ethnic' with '**minority**'. 9. When referencing 'obesity' to advise whether Use Case 4 also includes those considered to be 'overweight'. 10. To update section 5 to clarify if the vaccine stream of work will also include school vaccinations. The following advice was given: 1. IGARD noted the comments made by PAG:

	a. With reference to point 3, IGARD noted the comments made, but would also suggest further, that any engagement with GP Data Controllers is done through appropriate avenues. b. With reference to point 7, IGARD suggested that this is explored further by NHS Digital and appropriate stakeholders. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route.
2.2 (a)	<u>NHS North Lincolnshire Clinical Commissioning Group (CCG): GDPPR COVID-19 – CCG - Pseudo (Presenter: Duncan Easton) NIC-387297-J5L7M</u> **Background:** This was a new application from NHS North Lincolnshire CCG to receive data in support of the management of the COVID-19 emergency to receive GPES Data for Pandemic Planning and Research (GDPPR). The CCG will use the pseudonymised GDPPR COVID-19 data to provide intelligence to support their local response to the COVID-19 emergency. The data will be analysed so that health care provision can be planned to support the needs to the population within the CCG's area for COVID-19 purposes including, but not limited to, analysis of missed appointments, patient risk stratification and predictive text modelling, and resource allocation. **Discussion:** IGARD noted that an initial briefing on GPES Data for Pandemic Planning and Research (GDPPR) had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 21st April 2020. IGARD noted that the CCG GPES GDPPR pseudo templated content had been reviewed at the GPES GDPPR – Profession Advisory Group (PAG) on the 8th July (notes from that meeting had been attached to the IGARD minutes from the 9th July 2020), on the 15th July 2020 (see Appendix B), and tabled on the 5th August 2020 with no minutes produced. IGARD noted that the templated content for CCGs and Local Authorities had been previously presented to IGARD on the 28th May, 30th June 2020 and 9th July. IGARD noted and endorsed the comment made by PAG from the 15th July 2020, and with reference to point 3 "*The profession supports planning information to ensure services are appropriate and accessible, but data shared must not be used for the performance management of GP Practices*" and asked that an explicit statement be included in section 5 (Methods / Purpose / Outputs) clarifying that the data disseminated would **not** take the place of any usual performance management tools. IGARD noted and endorsed the comment made by PAG from the 15th July 2020, and with reference to point 4 "*In relation to GP appointments, there is an existing process around GP appointments (to be confirmed) led by NHS X SRO…GP data for planning must not replace this process*" and suggested that section 5 be updated to clarify that the applicant will have full regard to other initiatives that may be taking place and that the data disseminated should not be used as a substitution for said initiatives. IGARD noted the comment made by PAG from the 15th July 2020, and with reference to point 2 "*CCGs should be asked to provide updates to RCGP and BMA via the dedicated PAG mailbox (gppr.profadvisorygroup@nhs.net) on how the data has been used and should be at least once for 30th September and then quarterly thereafter*" and suggested that NHS Digital utilise the existing plans for developing the tracking of CCG yielded benefits, and suggested that NHS Digital work with the CCGs in developing this project, particularly in relation to GDPPR data.

	NHS Digital noted that with reference to point 6 "*PAG will be informed by NHSD if there are any particular considerations around the processors involved*." that this was a general point of process only and was not intended as a feedback loop to PAG. IGARD noted the update and suggested that all such processes be clearly delineated from general PAG comments or advice. IGARD were unclear from the application and briefing note provided if the re-identification of patients related to the re-identification of a 'groups of individuals' or an 'individual' and asked that section 1 (Abstract) and section 5 be updated to clarify. In addition, IGARD suggested that in section 5(b) (Processing Activities) and under the header "*Segregation*" and the sentence "*Where the Data Processor and / or Data Controller hold both the identifiable and pseudonymised data, the data will be held separately so data cannot be linked*…" that a clear statement be included as to how identification may take place if there is no linkage allowed under the application / Data Sharing Agreement (DSA). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that a special condition be inserted in section 6 (Special Conditions) that that the applicant should update and publish a General Data Protection Regulation (GDPR) compliant Privacy Notice, as assessed by NHS Digital and within 30 days of signing the Data Sharing Agreement (DSA) In addition, IGARD also suggested that special condition in section 6 starting "*The [disseminated (sic) data is confidential patient information and is provided by NHS Digital in confidence to the Data Controller….*" be updated to remove the plethora of "[" brackets since they appear to have been added in error, and to be clear that the data disseminated is in fact pseudonymised data but treated as confidential patient information (CPI). IGARD noted in section 5(a) (Objective for Processing) reference to "*SNOWMED*" and suggested this was updated to correctly reference the acronym "*SNOMED*". Referencing "…*Details of any sensitive SNOWMED (sic) codes can be found in the Reference Data and GDPPR COVID19 user guides hosted on the NHS Digital website*..." asked that a clear signpost be inserted as to how sensitive codes for SNOMED could be found in section 5(a) and to clarify whether or not those sensitive codes would be disseminated, with a clear statement again in section 5(a). IGARD noted that the briefing note had been finalised and provided as a supporting document however noted that it appeared to incorrectly reference a "*statutory duty*" and suggested that this be removed or qualified and before the briefing paper was presented again to IGARD as a supporting document. **Outcome:** recommendation to approve subject to the following condition: 1. To make clear throughout the application in respect of the re-identification of patients, if this is the re-identification of a 'group of individuals' or an 'individual(s)'. The following amendments were requested: 1. IGARD noted the comments made by PAG: o With reference to point 3, that section 5 be updated to clarify that the data disseminated would not take the place of usual performance management tools; o With reference to point 4, that section 5 be updated to clarify that the applicant will have full regard to other initiatives that may be taking place and the data disseminated should not be used in substitution. 2. To update section 5 to explain under the 'Segregation' heading how any such re-identification may take place if no linkage is allowed under this application.

	3. To insert a special condition in section 6 stating that within 30 days a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published. 4. To amend the special condition in section 6 to be clear that that data disseminated is pseudonymised but treated as CPI. 5. With regard to SNOMED and section 5: o To amend the acronym from 'SNOWMED' to 'SNOMED', o To clearly signpost how sensitive codes for SNOMED can be found, o To clarify whether or not those sensitive codes are disseminated. The following advice was given: 1. IGARD noted the comments made by PAG: o With reference to point 2, IGARD suggested that NHS Digital utilise the existing plans for developing the tracking of CCG yielded benefits and suggested that NHS Digital work with the CCGs in developing this project, particularly in relation to GDPPR data. IGARD noted the briefing paper had been previously finalised and was part of the supporting documentation, however, additional clarificatory points were raised by IGARD, and these would be noted within the ratified minutes. It was agreed the conditions would be approved OOC by the IGARD Chair.
2.2 (b)	<u>NHS Wakefield Clinical Commissioning Group (CCG): GDPPR COVID-19 – CCG - Pseudo (Presenter: Duncan Easton) NIC-384781-J8H2K</u> **Background:** This was a new application from NHS Wakefield CCG to receive data in support of the management of the COVID-19 emergency to receive GPES Data for Pandemic Planning and Research (GDPPR). The CCG will use the pseudonymised GDPPR COVID-19 data to provide intelligence to support their local response to the COVID-19 emergency. The data will be analysed so that health care provision can be planned to support the needs to the population within the CCG's area for COVID-19 purposes including, but not limited to, analysis of missed appointments, patient risk stratification and predictive text modelling, and resource allocation. **Discussion:** IGARD noted that an initial briefing on GPES Data for Pandemic Planning and Research (GDPPR) had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 21st April 2020. IGARD noted that the CCG GPES GDPPR pseudo templated content had been reviewed at the GPES GDPPR – Profession Advisory Group (PAG) on the 8th July (notes from that meeting had been attached to the IGARD minutes from the 9th July 2020), on the 15th July 2020 (see Appendix B), and tabled on the 5th August 2020 with no minutes produced. IGARD noted that the templated content for CCGs and Local Authorities had been previously presented to IGARD on the 28th May, 30th June 2020 and 9th July. IGARD noted and endorsed the comment made by PAG from the 15th July 2020, and with reference to point 3 "*The profession supports planning information to ensure services are appropriate and accessible, but data shared must not be used for the performance management of GP Practices*" and asked that an explicit statement be included in section 5 (Methods / Purpose / Outputs) clarifying that the data disseminated would **not** take the place of any usual performance management tools. IGARD noted and endorsed the comment made by PAG from the 15th July 2020, and with reference to point 4 "*In relation to GP appointments, there is an existing process around GP appointments (to be confirmed) led by NHS X SRO…GP data for planning must not replace*

	this process" and suggested that section 5 be updated to clarify that the applicant will have full regard to other initiatives that may be taking place and that the data disseminated should not be used as a substitution for said initiatives. IGARD noted the comment made by PAG from the 15th July 2020, and with reference to point 2 "*CCGs should be asked to provide updates to RCGP and BMA via the dedicated PAG mailbox (gppr.profadvisorygroup@nhs.net) on how the data has been used and should be at least once for 30th September and then quarterly thereafter*" and suggested that NHS Digital utilise the existing plans for developing the tracking of CCG yielded benefits, and suggested that NHS Digital work with the CCGs in developing this project, particularly in relation to GDPPR data. NHS Digital noted that with reference to point 6 "*PAG will be informed by NHSD if there are any particular considerations around the processors involved*." that this was a general point of process only and was not intended as a feedback loop to PAG. IGARD noted the update and suggested that all such processes be clearly delineated from general PAG comments or advice. IGARD were unclear from the application and briefing note provided if the re-identification of patients related to the re-identification of a 'groups of individuals' or an 'individual' and asked that section 1 (Abstract) and section 5 be updated to clarify. In addition, IGARD suggested that in section 5(b) (Processing Activities) and under the header "*Segregation*" and the sentence "*Where the Data Processor and / or Data Controller hold both the identifiable and pseudonymised data, the data will be held separately so data cannot be linked*…" that a clear statement be included as to how identification may take place if there is no linkage allowed under the application / Data Sharing Agreement (DSA). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that a special condition be inserted in section 6 (Special Conditions) that that the applicant should update and publish a General Data Protection Regulation (GDPR) compliant Privacy Notice, as assessed by NHS Digital and within 30 days of signing the Data Sharing Agreement (DSA) In addition, IGARD also suggested that special condition in section 6 starting "*The [disseminated (sic) data is confidential patient information and is provided by NHS Digital in confidence to the Data Controller….*" be updated to remove the plethora of "[" brackets since they appear to have been added in error, and to be clear that the data disseminated is in fact pseudonymised data but treated as confidential patient information (CPI). IGARD noted in section 5(a) (Objective for Processing) reference to "*SNOWMED*" and suggested this was updated to correctly reference the acronym "*SNOMED*". Referencing "…*Details of any sensitive SNOWMED (sic) codes can be found in the Reference Data and GDPPR COVID19 user guides hosted on the NHS Digital website*..." asked that a clear signpost be inserted as to how sensitive codes for SNOMED could be found in section 5(a) and to clarify whether or not those sensitive codes would be disseminated, with a clear statement again in section 5(a). IGARD noted that the briefing note had been finalised and provided as a supporting document however noted that it appeared to incorrectly reference a "*statutory duty*" and suggested that this be removed or qualified and before the briefing paper was presented again to IGARD as a supporting document. **Outcome:** recommendation to approve subject to the following condition: 1. To make clear throughout the application in respect of the re-identification of patients, if this is the re-identification of a 'group of individuals' or an 'individual(s)'.

	The following amendments were requested: 1. IGARD noted the comments made by PAG: a. With reference to point 3, that section 5 be updated to clarify that the data disseminated would not take the place of usual performance management tools; b. With reference to point 4, that section 5 be updated to clarify that the applicant will have full regard to other initiatives that may be taking place and the data disseminated should not be used in substitution. 2. To update section 5 to explain under the 'Segregation' heading how any such re-identification may take place if no linkage is allowed under this application. 3. To insert a special condition in section 6 stating that within 30 days a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published. 4. To amend the special condition in section 6 to be clear that that data disseminated is pseudonymised but treated as CPI. 5. With regard to SNOMED and section 5: a. To amend the acronym from 'SNOWMED' to 'SNOMED', b. To clearly signpost how sensitive codes for SNOMED can be found, c. To clarify whether or not those sensitive codes are disseminated. The following advice was given: 1. IGARD noted the comments made by PAG: a. With reference to point 2, IGARD suggested that NHS Digital utilise the existing plans for developing the tracking of CCG yielded benefits and suggested that NHS Digital work with the CCGs in developing this project, particularly in relation to GDPPR data. IGARD noted the briefing paper had been previously finalised and was part of the supporting documentation, however, additional clarificatory points were raised by IGARD, and these would be noted within the ratified minutes. It was agreed the conditions would be approved OOC by the IGARD Chair.
2.2 (c)	<u>NHS Birmingham and Solihull Clinical Commissioning Group (CCG): GDPPR COVID-19 – CCG - Pseudo (Presenter: Duncan Easton) NIC-387358-H3Z2J</u> **Background:** This was a new application from Birmingham and Solihull CCG to receive data in support of the management of the COVID-19 emergency to receive GPES Data for Pandemic Planning and Research (GDPPR). The CCG will use the pseudonymised GDPPR COVID-19 data to provide intelligence to support their local response to the COVID-19 emergency. The data will be analysed so that health care provision can be planned to support the needs to the population within the CCG's area for COVID-19 purposes including, but not limited to, analysis of missed appointments, patient risk stratification and predictive text modelling, and resource allocation. **Discussion:** IGARD noted that an initial briefing on GPES Data for Pandemic Planning and Research (GDPPR) had been previously seen by the IGARD – NHS Digital COVID-19 Response meeting on the 21st April 2020. IGARD noted that the CCG GPES GDPPR pseudo templated content had been reviewed at the GPES GDPPR – Profession Advisory Group (PAG) on the 8th July (notes from that meeting had been attached to the IGARD minutes from the 9th July 2020), on the 15th July 2020 (see Appendix B), and tabled on the 5th August 2020 with no minutes produced.

	IGARD noted that the templated content for CCGs and Local Authorities had been previously presented to IGARD on the 28th May, 30th June 2020 and 9th July. IGARD noted and endorsed the comment made by PAG from the 15th July 2020, and with reference to point 3 "*The profession supports planning information to ensure services are appropriate and accessible, but data shared must not be used for the performance management of GP Practices*" and asked that an explicit statement be included in section 5 (Methods / Purpose / Outputs) clarifying that the data disseminated would **not** take the place of any usual performance management tools. IGARD noted and endorsed the comment made by PAG from the 15th July 2020, and with reference to point 4 "*In relation to GP appointments, there is an existing process around GP appointments (to be confirmed) led by NHS X SRO…GP data for planning must not replace this process*" and suggested that section 5 be updated to clarify that the applicant will have full regard to other initiatives that may be taking place and that the data disseminated should not be used as a substitution for said initiatives. IGARD noted the comment made by PAG from the 15th July 2020, and with reference to point 2 "*CCGs should be asked to provide updates to RCGP and BMA via the dedicated PAG mailbox (gppr.profadvisorygroup@nhs.net) on how the data has been used and should be at least once for 30th September and then quarterly thereafter*" and suggested that NHS Digital utilise the existing plans for developing the tracking of CCG yielded benefits, and suggested that NHS Digital work with the CCGs in developing this project, particularly in relation to GDPPR data. NHS Digital noted that with reference to point 6 "*PAG will be informed by NHSD if there are any particular considerations around the processors involved*." that this was a general point of process only and was not intended as a feedback loop to PAG. IGARD noted the update and suggested that all such processes be clearly delineated from general PAG comments or advice. IGARD were unclear from the application and briefing note provided if the re-identification of patients related to the re-identification of a 'groups of individuals' or an 'individual' and asked that section 1 (Abstract) and section 5 be updated to clarify. In addition, IGARD suggested that in section 5(b) (Processing Activities) and under the header "*Segregation*" and the sentence "*Where the Data Processor and / or Data Controller hold both the identifiable and pseudonymised data, the data will be held separately so data cannot be linked*…" that a clear statement be included as to how identification may take place if there is no linkage allowed under the application / Data Sharing Agreement (DSA). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and suggested that a special condition be inserted in section 6 (Special Conditions) that that the applicant should update and publish a General Data Protection Regulation (GDPR) compliant Privacy Notice, as assessed by NHS Digital and within 30 days of signing the Data Sharing Agreement (DSA) In addition, IGARD also suggested that special condition in section 6 starting "*The [disseminated (sic) data is confidential patient information and is provided by NHS Digital in confidence to the Data Controller….*" be updated to remove the plethora of "[" brackets since they appear to have been added in error, and to be clear that the data disseminated is in fact pseudonymised data but treated as confidential patient information (CPI). IGARD noted in section 5(a) (Objective for Processing) reference to "*SNOWMED*" and suggested this was updated to correctly reference the acronym "*SNOMED*". Referencing "…*Details of any sensitive SNOWMED (sic) codes can be found in the Reference Data and GDPPR COVID19 user guides hosted on the NHS Digital website*..." asked that a clear

	signpost be inserted as to how sensitive codes for SNOMED could be found in section 5(a) and to clarify whether or not those sensitive codes would be disseminated, with a clear statement again in section 5(a). IGARD noted that the briefing note had been finalised and provided as a supporting document however noted that it appeared to incorrectly reference a "*statutory duty*" and suggested that this be removed or qualified and before the briefing paper was presented again to IGARD as a supporting document. **Outcome:** recommendation to approve subject to the following condition: 1. To make clear throughout the application in respect of the re-identification of patients, if this is the re-identification of a 'group of individuals' or an 'individual(s)'. The following amendments were requested: 1. IGARD noted the comments made by PAG: c. With reference to point 3, that section 5 be updated to clarify that the data disseminated would not take the place of usual performance management tools; d. With reference to point 4, that section 5 be updated to clarify that the applicant will have full regard to other initiatives that may be taking place and the data disseminated should not be used in substitution. 2. To update section 5 to explain under the 'Segregation' heading how any such re-identification may take place if no linkage is allowed under this application. 3. To insert a special condition in section 6 stating that within 30 days a GDPR-compliant Privacy Notice, as assessed by NHS Digital, will be published. 4. To amend the special condition in section 6 to be clear that that data disseminated is pseudonymised but treated as CPI. 5. With regard to SNOMED and section 5: d. To amend the acronym from 'SNOWMED' to 'SNOMED', e. To clearly signpost how sensitive codes for SNOMED can be found, f. To clarify whether or not those sensitive codes are disseminated. The following advice was given: 1. IGARD noted the comments made by PAG: b. With reference to point 2, IGARD suggested that NHS Digital utilise the existing plans for developing the tracking of CCG yielded benefits and suggested that NHS Digital work with the CCGs in developing this project, particularly in relation to GDPPR data. IGARD noted the briefing paper had been previously finalised and was part of the supporting documentation, however, additional clarificatory points were raised by IGARD, and these would be noted within the ratified minutes. It was agreed the conditions would be approved OOC by the IGARD Chair.
2.3	<u>Genomics England: R-26 GENOMICS ENGLAND: GenOMICC COVID-19 Study (Presenter: Louise Dunn) NIC-374190-D0N1M</u> **Background:** This was a new application for identifiable Mental Health Services Data Set (MHSDS), Community Services Data Set (CSDS), Civil Registration (death), Demographics, COVID-19 Hospitalization in England Surveillance System (CHESS), Hospital Episode Statistics (HES), Diagnostic Imaging Dataset (DID), Emergency Care Data Set (ECDS), COVID-19 Second Generation Surveillance System (SGSS), Secondary Uses Service

	Payment by Result (SUS PBR), Cancer Registration Data and GPES Data for Pandemic Planning and Research (GPDPPR). The purpose is for a national study aiming to provide detailed whole genome sequencing to 35,000 participants affected by COVID-19 and it is the aim to concurrently add high quality clinical data to aid the research effort; and would be available for analysis alongside the extant Genomics England data set of the 100,000 Genomes Project. The application had been previously considered on the 25th June 2020 when IGARD had deferred making a recommendation pending: In respect of the specific points raised by PAG: a) To clearly describe the control cohort and address via the special condition in section 6, what can and cannot be undertaken with the control cohort (including that the control cohort cannot be analysed in isolation), b) NHS Digital IG to provide confirmation of the legal basis and how it relates to the processing outlined in the application which appears to indicate research beyond the COPI scope (and NHS Digital to work with the applicant to revise the consent materials to cover the points raised by both IGARD and PAG), c) Although IP / commercial is not relevant to this application (as University of Edinburgh is the only onward recipient), this could be addressed in the transparency and consent materials in due course; NHS Digital IG to provide confirmation of the legal basis for the University of Edinburgh to have access to the pseudonymised data and specifically that a Scottish Data Controller is not precluded by the geographical restrictions of COPI from accessing data originally gathered under that legal basis; To update the application throughout to clarify the cohort size, for example, how many participants have been included now, how many are planned to be recruited in the future (including but not limited to) the reference to the size of the cohort described in section 5; To be explicitly clear in section 5(a) and throughout the application which aspects relate to the COVID-19 purpose which is relying on the COPI notice, noting the description of the specific COVID-19 study as set out in the Protocol (with ethics approval) is narrower than the COVID-19 description provided in section 5; To provide justification clearly linking the datasets requested with the study purpose and particular attention should be paid to the significant size and scope of the GP data, and whether further data minimisation could take place, for example, narrowing diagnosis codes etc; To clarify if GP data is also flowing for the 100,000 Genomes Control Group; To clarify if the composition of the 100,000 Genomes Control Group is an appropriate control group for a study of this nature, bearing in mind that many of the control group will have cancer or a rare disease; To provide a rationale for the flow of identifiers back to Genomics England from NHS Digital; To update the application throughout to be clear what benefits will flow from this narrow COVID-19 study; To update section 5(b) to clarify at which point this data will start to be processed, for example, when a critical mass of participants has been reached; To provide clarification of what will happen if a participant is in both the study group and the control group, and if NHS Digital will filter these participants; IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment; IGARD suggested that this application would not be suitable for NHS Digital's precedent route **Discussion:** IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 28th April, 5th May, 12th May, 16th June, 23rd June and 14th July 2020. IGARD noted that this application had been reviewed at the GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) on the 17th June 2020 (notes from that meeting had been attached to the IGARD minutes from the 25th June 2020) and on the 29th July 2020 (see Appendix B). IGARD noted that the application had been extensively re-written since the last review and discussed the PAG notes in detail.

	IGARD noted and endorsed the comment made by PAG from the 29th July 2020, and with reference to point 4 "*PAG have seen details in relation to the 'Prior Principle' (SD19 within the application pack) and would ask GEL to include it within the commercial section of the application*" and suggested that section 5(e) (Is the Purpose of this Application in Anyway commercial?) be updated to include reference to 'Prior Principle', which is the principle laid out by Lord Prior as part of the invitation to join the consortium of academic and industrial researchers which states "*if your organisation is successful in identifying a therapy of vaccine as a result of this programme you would offer it on preferential access and pricing terms to the NHS*". IGARD noted and endorsed the comment made by PAG from the 29th July 2020, and with reference to point 3 "*PAG noted the potential use of the data for risk scores (5d). If risk calculators or algorithms were to be generated from the data, this should be done in conjunction with MHRA*" and asked that a special condition be inserted in section 6 (Special Conditions) that clearly set out that if calculation or algorithms were generated, consideration should be given to doing this in conjunctions with the Medicines and Healthcare products Regulatory Agency (MHRA) or another appropriate body. Noting that the legal basis to disseminate the data was under The Health Service Control of Patient Information (COPI) Regulations 2002, IGARD noted that the application did not align with the relevant supporting documents provided as part of the review. IGARD suggested that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) be updated to align the stated purpose with the legal basis and that only the permitted activities under this Data Sharing Agreement (DSA) were for COVID-19 purposes and within the bounds of Regulation 3(2) COPI. In addition, IGARD suggested that a special condition be inserted in section 6 (Special Condition) which outlined the restrictions that the only permitted activities under this application / DSA are for COVID-19 purposes and within the bounds of Regulation 3(2) COPI. IGARD also queried the substantial future use of data text narrative in section 5, and suggested that this was ether clearly delineated as aspirational, or to remove the narrative text for a future amendment application. Noting the legal basis to disseminate the data was under COPI, IGARD asked for written confirmation from NHS Digital that the Data Processors: UK Cloud and Amazon Web Services were processing confidential patient information (CPI); if they were processing CPI to clearly state how the applicant satisfied Regulation 7(2) of COPI; and to upload a copy of the written evidence to the NHS Digital Customer Relationship Management (CRM) system for future reviews. IGARD noted that the Legitimate Interest Assessment (LIA) document should be reviewed by NHS Digital and that confirmation be inserted in section 1 that such a review has been undertaken and that it has been updated to reflect that consent is not the legal basis for the dissemination of data under this application / DSA. Noting the amount of data requested under this application, IGARD suggested the applicant consider incorporating in the Access Review Committee (ARC) Terms of Reference (TOR), an express point addressing data minimisation and how applicants have considered this legal requirement, reflecting NHS Digital's Standard on Data Minimisation. IGARD noted reference in section 1 to "…*that these be submitted to the Research Ethics Committees (REC) in England and Scotland*…" in reference to the updated supporting documentation received, and suggested that this statement be updated to insert a definitive

	statement with regard to the current ethics approval process, referencing the current ethics approval supporting documents. IGARD noted a number of acronyms were noted in section 1 and section 5 and asked that this public facing section be updated to ensure that all acronyms upon first use were expanded and clearly defined with a supportive explanation in a language suitable for a lay reader, for example "WGS". In addition, IGARD suggested that the language in section 5 be updated to reflect that they '*hope*' to ultimately influence the patient care, rather than '*will*'. IGARD noted reference in section 5(a) (Objective for Processing) to "*UK Biobank data sets*" and "*UK Biobank cohort*" and suggested that the application be updated to clarify the reference to UK Biobank as a future use, or remove it if not currently relevant. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices and that a special condition had been inserted in section 6 (Special Conditions) that the applicant would provide "*an adequate*" General Data Protection Regulation (GDPR) compliant Privacy Notice, as assessed by NHS Digital and within 1 month of signing the Data Sharing Agreement (DSA). In addition IGARD suggested that the last listed special condition "*Access to data internationally is restricted to the territory of use as set out in this agreement*" since the point was adequately covered in a previous special condition in section 6. IGARD noted that the applicant already had a robust patient and public involvement (PPI) panel and suggested that the applicant may wish to consider whether the Forum could also benefit from patient representatives. In addition, further clarification was sought in section 5 at what point and how patients with COVID-19 were added to the participation group, since it was not clear in the application or SDs provided as part of this review. IGARD noted a number of benefits had been outlined in section 5(d) (Benefits) but suggested that these be refined and updated to ensure they were both realistic and achievable within the timeframe of the DSA and data under this application. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's precedent route, including the use of the SIRO precedent due to the GDPPR data. **Outcome:** recommendation to approve subject to the following conditions: 1. With reference to PAG point 4, to update section 5(e) to include reference to 'Prior Principle'. The following amendments were requested: 1. IGARD noted the comments made by PAG: a) With reference to point 3, to insert a special condition in section 6 that if risk calculations or algorithms are generated, consideration should be given to doing this in conjunction with MHRA or another appropriate body. 2. To update section 1 to confirm that NHS Digital have reviewed the LIA and are content (ensuring that the LIA has been updated to reflect that consent is not the legal basis for this dissemination). 3. To amend section 5 to ensure that all acronyms upon first use within the document and within the published sections be defined and further explained, as may be necessary for a lay reader. 4. To update the application to align the stated purpose with the legal basis: a) namely that the only permitted activities under this DSA are for COVID-19 purposes and within bounds of Reg 3(2) COPI.

	b) To insert a special condition in section 6 setting outlining these restrictions as per 5(a) above. c) If retaining narrative about possible future use of data, to clearly delineate as aspirational or to remove such narrative. 5. To amend section 1 to insert a definitive statement with regard to the current ethics approval process, referencing the current ethics approval SDs. 6. To update the application to clarify the reference to "Biobank" as a future use, or remove if not currently relevant. 7. To clarify in section 5 at what point and how patients with COVID-19 are added to the participation group. 8. To revise the language in section 5(d) to ensure that the benefits are realistic and achievable, in line with the data flowing. 9. To remove the final listed special condition in section 6 that starts "*Access to data*…" since the point is adequately covered elsewhere. 10. NHS Digital to confirm in writing with regard to UK Cloud and Amazon Web Services a) To confirm if they process CPI; b) If so, how they satisfy Reg 7(2) of COPI c) To upload a copy of the IG written advice to CRM The following advice was given: 1. IGARD noted the robust PPI panel but also asked the application to consider whether the 'Forum' could also benefit from patient representatives. 2. IGARD suggest the applicant consider incorporating in the ARC TOR an express point addressing data minimisation and how applicants have considered this legal requirement. 3. IGARD suggested that the language in section 5 be updated to reflect that they 'hope' to ultimately influence the patient care, rather than 'will'. 4. IGARD advised that they would wish to review this application again when it comes up for renewal, extension or amendment 5. IGARD suggested that this application would not be suitable for NHS Digital's precedent route including the use of the SIRO precedent due to the GDPPR data. It was agreed the conditions would be approved OOC by the IGARD Chair
2.4	<u>National Institute for Health Research (NIHR) BioResource: R7.1 HDRUK consented research cohorts – identify susceptibility and resilience factors in cohorts – data (HES & Mortality on IBD & blood donors) (Presenter: Kimberley Watson) NIC-374223-P4P4L</u> **Background:** This was a new application for identifiable Civil Registration (death) data, Hospital Episode Statistics (HES) Critical Care (CC), HES Accident & Emergency (A&E), HES Outpatients, HES Admitted Patient Care (APC), Emergency Care Data Set (ECDS) and COVID-19 Hospitalisation in England Surveillance System (CHESS). The NIHR BioResource Centre has been recruiting patients with inflammatory bowel disease (IBD) since 2017 and has over 34,000 participants, recruited from over 100 NHS Trusts in England, 1 site in Scotland and 2 sites in Wales and is seeking data on these IBD patients for two urgent COVID-19 related research questions: 1) what is the outcome (hospital admission / intensive care unit admission / death) for patients with IBD on the immunosuppressant or any-TNF therapies who test positive for COVID-19? Are their outcomes worse, the same or possibly better than matched people with IBD but not on the drug and 2) what are the risk factors, including genetic risk factors, associated with susceptibility to, and severity of, infection?

	Discussion: IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 19th May, 2nd June, 9th June and 16th June 2020. IGARD noted patients had been informed about re-identification via the Patient Information Sheet (PIS) when recruited to the IBD study, however it was not clear in the application, and suggested that Section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) be updated to clearly state the process of re-identification and how this aligned with the re-identification instances that patients had been informed about via the PIS. IGARD noted in section a that "*the Shielded Patient List is no longer being requested*" however in section 5(a) (Objective for Processing) it stated "*some were placed in the high risk group (according to the Shielded Patient List, to which IBD clinicians contributed)…*" and in section 5(d)(ii) (Expected Measurable Benefits to Health and / or Social Care including target date) "*the risk stratification tool used to place IBD patients on the Shielded Patient List may change…*" and suggested that the application be updated throughout to ensure it accurately reflected that the application and Data Sharing Agreement (DSA) was not receiving data from the Shielded Patient List (SPL). Noting the magnitude and impact of IBD on patients, IGARD suggested that in addition to patient involvement noted within the application, that the applicant consider prospective patient involvement in the study design, study management and developing the revised consent materials. In addition, that section 5 be further updated to consider the potential wider impact of the study outcomes than just those patients with IBD. IGARD noted that the title of the application referenced "*IBD and blood donors*" and suggested amending the title to remove reference to 'blood donors' since they were not part of this application or Data Sharing Agreement and that the NHS Digital Customer Relationship Management (CRM) system be updated to reflect it. IGARD noted that in section 1 (Abstract) the NIHR BioResource Centre had recruited over 34,000 participants, however the cohort size for this application / Data Sharing Agreement (DSA) was 30,802, and suggested that a clear narrative be included that those 3,000 approximate participants not included, had been recruited on earlier versions of consent materials and were not part of this study. In addition, and noting that an assessment had been undertaken by NHS Digital on the consent materials provided, IGARD noted that further work should be undertaken by the applicant to augment the current consent materials by providing an updated newsletter to all the participant and continuing to work with NHS Digital to update and improve the consent materials further. IGARD noted that the legal basis noted on in supporting document 2, network diagram, referenced an incorrect legal basis and that the document should be updated. IGARD noted reference in section 5(c) (Specific Outputs Expected, including Target Date) to "t*he target is as soon as possible…*" and suggested that this was updated with a more indicative timeframe. IGARD suggested that the table in section 3(b) (Additional Data Access Requested) should be updated to correctly reference both the 'sensitivity' and 'identifiability' of the data being disseminated, since they were not listed consistently IGARD suggested that NHS Digital review section 11 (Charges) since they appeared to be a miscalculation. **Outcome:** recommendation to approve subject to the following condition:

	1. To make clear throughout the application the process of re-identification and how this aligns with the re-identifications instances that patients were informed of via the PIS. The following amendments were requested: 1. To update the legal basis on the data flow diagram. 2. To query the charges associated with this application. 3. To update the title of this application in CRM to remove reference to 'blood donors'. 4. To update section 1 to clarify the cohort number discrepancy. 5. To update the tables in section 3 to correctly list the 'identifiability' and 'sensitivity' of each data set. 6. To edit the application to ensure it accurately reflects that that the application is **not** receiving data from SPL. 7. To update section 5 to consider that the impact could be wider than just those patients with IBD. 8. To update section 5 with a specific indicative timeframe target rather than 'asap'. The following advice was given: 1. IGARD noted that the applicant should continue to work with NHS Digital on their consent materials. 2. IGARD noted that in addition to patient involvement noted in the application that the applicant consider prospective patient involvement in the study design, study management and developing the revised consent materials. It was agreed the conditions would be approved OOC by the IGARD Chair (plus the Specialist Ethics Member)
2.5	<u>University College London (UCL) (Centre for Longitudinal Studies): 1958 National Child Development Study (Presenter: Kimberley Watson) NIC-49297-Q7G1Q</u> **Background:** this was extension to UCL's Institute for Education: Centre for Longitudinal Studies (CLS) birth cohort studies data linkage '1958 National Child Development Study' (NCDS) (also known as the 1958 British Cohort Study) which expired on the 30th April 2020; and an amendment to update the purpose section to reflect the inclusion of a sub-licensing model. The application shares the same footprint as NIC-51342-V1M5W University College London 'Next Steps Age 25 Cohort' and NIC-49826-T0J7C University College London '1970 British Cohort Study' and together the three applications form part of the CSL longitudinal study portfolio. No new data is being requested under this application and the applicant is wanting to retain their current data of Hospital Episode Statistics (HES) Accident & Emergency (A&E), HES Outpatient (OP), HES Critical Care (CC) and HES Admitted Patient Care (APC) which is linked with the NCDS cohort of 6,529 participants who consented to the linkage and use of their health data for the purposes of research. The NCDS study follows the lives of over 17,000 people born in England, Scotland and Wales in a single week of 1958 and collects information on physical and educational development, economic circumstances, employment, family life, health behaviour, wellbeing, social participation and attitudes. **Discussion:** IGARD noted that this application (NIC-49297-Q7G1Q) was part of a group of three similar applications, and suggested that when it is presented to a future IGARD, it should continue to come as a suite of applications with NIC-51342-V1M5W and NIC-49826-T0J7C There was a lengthy discussion with regard to how the applicant had met the NHS Digital Standard for Sub Licencing and IGARD suggested that written confirmation be provided as to

	how the applicant had met each of the points in said Standard and if addressed, where in the application or supporting documents it had been addressed. IGARD noted that the study website referenced the researchers having to present a strong scientific case for the wider value to the society, however this was not noted within the 'CLS DAC Committee Terms of Reference (TOR)' and suggested that the TOR be updated to specifically reflect the sub-licencing application, including but not limited to, an express statement addressing data minimisation (as per NHS Digital's Standard for Data Minimisation) and how the data will be for benefit to health and social care. IGARD noted in section 5(a) (Objective for Processing) reference to "…*CLS will be the data controller…*" and "…*an agreement between CLS (as a data controller)*…" however since CLS is not a legal entity, to remove reference to CLS being a data controller and replacing or including as appropriate with the correct legal entity of 'UCL'. IGARD suggested that section 5(c) (Specific Outputs Expected including Target Date) be updated to remove the sentence which starts "*the outputs in the long term from this linked dataset are difficult to quantify…"* and suggested that the text following indicating the searchable biography was sufficient. Noting that not all "*lifestyle choices*" are in fact 'choices' to update the language in section 5 (Purpose / Methods / Outputs) to update the reference and use another form of words. IGARD noted inconsistencies where referencing 'territory of use' across the application, DSA, Data Sharing Framework Contract (DSFC) and sub-licence supporting documentation and asked that they were aligned and consistent, since the territory of use was England / Wales. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's precedent route. **Outcome:** recommendation to approve subject to the following conditions: 1. To provide written confirmation how the applicant has met DARS Standard for Sub Licencing. 2. To update the applicant's TOR provided to reflect the questions on the sub-licensing application, including express consideration of data minimisation and how the data will be of benefit to health and social care. The following amendments were requested: 1. To remove reference to 'CLS' being a data controller in section 5 and replace or include as appropriate with the correct legal entity 'UCL'. 2. To remove from section 5(c) the sentence which starts '*the outputs in the long term from this linked dataset are difficult to quantify…'*. 3. To update reference to '*lifestyle choices'* to another form of wording, since they may not necessarily be 'choices'. 4. To ensure the 'territory of use' is consistent across the DSA, DSFC and sub licences. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. 3. IGARD noted that when this application (NIC-49297-Q7G1Q) is presented again, it should come as a suite of applications with NIC-51342-V1M5W and NIC-49826-T0J7C.

	It was agreed the conditions would be approved OOC by IGARD Members
2.6	University College London (Centre for Longitudinal Studies): Next Steps Age 25 Study (Presenter: Kimberley Watson) NIC-51342-V1M5W **Background:** this was an extension to UCL's 'Next Steps Age 25 Study' which expired on the 31st July 2020 (previously known as the Longitudinal Study of Young People in England (LSYPE). The application shares the same footprint as NIC-49297-Q7G1Q University College London ' 1958 National Child Development Study' and NIC-49826-T0J7C University College London '1970 British Cohort Study' and together the three applications form part of the CSL longitudinal study portfolio. No new data is being requested under this application and the applicant is wanting to retain their current data of Hospital Episode Statistics (HES) Accident & Emergency (A&E), HES Outpatient (OP), HES Critical Care (CC) and HES Admitted Patient Care (APC) which is linked with the cohort of 4,941 participants who are subject of the data linkage and onward sharing, and who were born in 1989 / 1990. The Next Steps Study began in 2004 and has collected information about the cohort's education and employment, economic circumstances, family life, physical and emotional health and wellbeing, social participation and attitudes. Following the group into adulthood will improve understanding of how experiences as teenagers affect later life and to evaluate the success of policies aimed at this group of young adults. **Discussion:** IGARD noted that this application (NIC-51342-V1M5W) was part of a group of three similar applications, suggested that when it is presented to a future IGARD, it should continue to come as a suite of applications with NIC-49297-Q7G1Q and NIC-49826-T0J7C. There was a lengthy discussion with regard to how the applicant had met the NHS Digital Standard for Sub Licencing and IGARD suggested that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) was updated to clarify that no sub-licences had been granted under this application / Data Sharing Agreement (DSA); to clarify why no sub-licences had been granted, since it was not clear in the application or supporting documentation and to clarify when the applicant anticipated the sub-licences being granted and the likely quantum of sub-licences. IGARD noted that the 'CLS DAC Committee Terms of Reference (TOR)' be updated to specifically reflect the sub-licencing, including but not limited to, an express statement of data minimisation (as per NHS Digital's Standard for Data Minimisation) and how the data will be for benefit to health and social care and as outlined in the update under NIC-49297-Q7G1Q. IGARD suggested that section 5(c) (Specific Outputs Expected including Target Date) be updated to remove the sentence which starts "*the outputs in the long term from this linked dataset are difficult to quantify…"* and suggested that the text following indicating the searchable biography gave sufficient examples. IGARD noted inconsistencies where referencing 'territory of use' across the application, DSA, Data Sharing Framework Contract (DSFC) and sub-licence supporting documentation and asked that they were aligned and consistent, since the territory of use was England / Wales. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's precedent route. **Outcome:** recommendation to approve. The following amendments were requested:

	1. To update section 1 and section 5 to a. clarify that no sub licences have been granted, b. why they have not yet been granted, and c. when they anticipate the sub licences to be granted and the likely quantum. 2. To update the applicant's TOR to reflect the questions asked in the sub-licensing application, and if relevant incorporating any changes as outlined in the update under NIC-49297-Q7G1Q 3. To ensure the 'territory of use' is consistent across the DSA, DSFC and sub licences. 4. To remove from section 5(c) the sentence which starts '*the outputs in the long term from this linked dataset are difficult to quantify…'*. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. 3. IGARD noted that when this application (NIC-51342-V1M5W) is presented again, it should come as a suite of applications with NIC-49297-Q7G1Q and NIC-49826-T0J7C.
2.7	University College London (Centre for Longitudinal Studies): 1970 British Cohort Study (Presenter: Kimberley Watson) NIC-49826-T0J7C **Background:** this was extension to UCL's '1970 British Cohort Study' (BCS70) which expired on the 1st April 2020; and an amendment to update the purpose section to reflect the inclusion of a sub-licensing model. The application shares the same footprint as NIC-51342-V1M5W University College London 'Next Steps Age 25 Cohort' and NIC-49297-Q7G1Q University College London '1958 National Child Development Study' and together the three applications form part of the CSL longitudinal study portfolio. No new data is being requested under this application and the applicant is wanting to retain their current data of Hospital Episode Statistics (HES) Accident & Emergency (A&E), HES Outpatient (OP), HES Critical Care (CC) and HES Admitted Patient Care (APC) which is linked with the 'Age 42' cohort of 6,181 participants who consented to the linkage and use of their health data for the purposes of research. The BCS70 was created in response to concerns about the health and life changes of babies being born at that time and information was collected on about 17,000 babies born in a single week in 1970 and this became the first wave of BCS70. Since birth there have been nine further studies at ages 5, 10, 16, 2, 30, 34, 38, 42, 46 and an upcoming 50. **Discussion:** IGARD noted that this application (NIC-49826-T0J7C) was part of a group of three similar applications, and suggested that when it is presented to a future IGARD, it should continue to come as a suite of applications with NIC-49297-Q7G1Q and NIC-51342-V1M5W. IGARD noted that the 'CLS DAC Committee Terms of Reference (TOR)' be updated to specifically reflect the sub-licencing, including but not limited to, an express statement of data minimisation (as per NHS Digital's Standard for Data Minimisation) and how the data will be for benefit to health and social care and as outlined in the update under NIC-49297-Q7G1Q. IGARD suggested that section 5(c) (Specific Outputs Expected including Target Date) be updated to remove the sentence which starts "*the outputs in the long term from this linked dataset are difficult to quantify…"* and suggested that the text following indicating the searchable biography gave sufficient examples.

	IGARD noted inconsistencies where referencing 'territory of use' across the application, DSA, Data Sharing Framework Contract (DSFC) and sub-licence supporting documentation and asked that they were aligned and consistent, since the territory of use was England / Wales. IGARD suggested that they would wish to review this application again when it comes up for renewal, extension or amendment; and that this application would not be suitable for NHS Digital's precedent route. **Outcome:** recommendation to approve. The following amendments were requested 1. To update the applicant's TOR to reflect the questions asked in the sub-licensing application, and if relevant incorporating any changes as outlined in the update under NIC-49297-Q7G1Q. 2. To ensure the 'territory of use' is consistent across the DSA, DSFC and sub licences. 3. To remove from section 5(c) the sentence which starts '*the outputs in the long term from this linked dataset are difficult to quantify…'*. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route. 3. IGARD noted that when this application (NIC-49826-T0J7C) is presented again, it should come as a suite of applications with NIC-49297-Q7G1Q and NIC-51342-V1M5W.
3	<u>Returning Applications</u> Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
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 The Health Service Control of Patient Information (COPI) Regulations 2002 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 4th August can be found attached to these minutes as Appendix C. 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 31/07/20

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-180665-GJMW5	University College London	02/07/2020	1. To provide a copy of the original HRA CAG application and any further amendment applications submitted to HRA CAG, to support the fact that this is now a longitudinal study into a wide variety of factors and health outcomes, not just mortality.	IGARD members	Quorum of IGARD members	None
NIC-68697-R6F1T	Dr. Foster Limited	25/06/2020	1. To inset a special condition in section 6, stating that Dr.Foster Limited may not flow NHS Digital data to NHS England / NHS Improvement unless they are in receipt of a DPIA that expressly addresses receipt of GIRFT outputs with small numbers unsuppressed. 2. In respect of the 2 years overlap of the ECDS and HES A&E data, to either provide a detailed justification of having 2 full years of (largely) duplicated data, or to produce a shorter timeframe to carry out the requisite checks, with the option to request further data for comparison purposes if necessary.	IGARD members	Quorum of IGARD members	None
NIC-13906-G0F3F	Healthcare Information Network	02/07/2020	1. To provide a clear justification of how the stated Article 6 legal basis can be relied on for all aspects of the processing beyond the scope of the CMA Order, for example in	IGARD Chair	IGARD Chair	None

			relation to addressing the CQC queries as outlined in section 5(a), which relate to PHIN's wider functions, not just those set out in the Order.			
NIC-192305-X3T0Y	NHS England (Quarry House)	09/07/2020	1. To provide written confirmation that NHS England have carried out a DPIA, that addresses (amongst other things) the sharing of aggregated data with small numbers unsuppressed and the risk of re-identification.	IGARD Chair	IGARD Chair	None
NIC-381078-Y9C5K	Health Data Research UK	23/07/20	1. To provide a satisfactory exploration of the ethical issues related to the publication of practitioner level data and how this will be managed.	IGARD members	Quorum of IGARD members	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 Oversight and Assurance Report.

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

- NIC-49735-Q6G7J NHS Kernow CCG

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 5th August 2020

Application: DARS-NIC-384608-v0.7
Organisation name: NHS England
Profession Advisory Group Agenda item:2

A Conflict of Interest was declared by Amir Mehrkar who has an interest in NHS England's OpenSafely C19 Research Platform, which is another data set of significant GP Data under NHS England's data controllership. In view of this, Amir Mehrkar was in observer status and nominated Marcus Baw (HIG RCGP chair) to inform the discussions. The Chair has agreed for Marcus Baw to join PAG to represent RCGP in addition to Amir Mehrkar's (observer) attendance.

PAG noted the importance and significance of NHS England's application: as the national commissioning organisation, NHS England conducts a critical role in using data to improve patient outcomes in relation to the pandemic. PAG is committed to supporting NHS England, and noted that the application had been substantively rewritten, improved and with helpful clear details.

Notably, the areas addressed from the original application were:

1. NHS England and NHS Improvement are joint data controllers.
2. There will be no onward dissemination of GP Data out of NHS England.
3. There was explicit mention of a data processor which would not have access to the GP data.
4. There was no longer any mention of sublicensing.
5. NHS England gave further detail on the anticipated use cases.

The following issues were identified by PAG:

1. In order to satisfy ourselves that all alternative avenues (to large data transfers) have been fully explored, PAG respectfully request that NHS England to provide documentary evidence of a discussion with each of the available Trusted Research Environments (including NHS Digital's TRE and the TRE already established by NHS England OpenSAFELY) establishing that these TREs would be **unable** to satisfy the needs of NHS England in regard its responsibilities around research and planning as applicable to the COVID-19 pandemic, and would be unable to develop such capability within a reasonable time-frame. This is in order to reduce unnecessary dissemination of highly disclosive GP data, and would help satisfy the professional need for data minimisation.
2. PAG recommend NHS Digital and NHS England prioritise and fund the enhancement their existing strategic TRE solution(s) to allow NHS England to execute its functions in future whilst minimising transfer of disclosive GP data.
3. The PAG expects that whichever route is taken, there will continue to be full and proper engagement with the profession via JGPITC and GP data controllers, proper safeguards on access to data, whether that be in NHSE or a TRE, and that all IG and legal issues are satisfactorily addressed, as was the case with the GPES process and the GP Data for Research and Planning programme.
4. There still remains a need to uplift the Privacy Notice.

5. PAG requested that the statement within section 3C be amended to make clear that Type 1 opt-outs would be upheld in relation to GP data.
6. PAG also requested that on page 21 it was made explicit that PHE will not have access to the GP data. Also that it is explicit that the approval route for GP data linkage was through NHS England's approval team to ensure that COPI was appropriately applied and related to data provided by NHS Digital.
7. PAG wished to advise IGARD that we feel that as a general position, any and all derived intellectual property (such as machine learning models, AI, and algorithms, etc) from the GP data must remain the property of the NHS (and ideally open-sourced or otherwise published for maximum public and professional benefit). This clause should cascade down through any processing arrangements.
8. PAG advised that the scale and nature of this new processing activity warrants open publication of an updated Data Protection Impact Assessment.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar (Observer)	GP, Clinical Researcher	RCGP
Marcus Baw	GP	RCGP
Julian Costello	GP	RCGP
Pam Soorma	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 15th July 2020

Application: DARS-NIC-384781-J8H2K-v0.2 **Organisation name: NHS North Lincolnshire CCG** **Profession Advisory Group Agenda item: 4**
PAG supported the application, with the following comments: 2. IGARD's attention were drawn to the need for CCG's to have a transparency notice 3. CCGs should be asked to provide updates to RCGP and BMA via the dedicated PAG mailbox (gppr.profadvisorygroup@nhs.net) on how the data has been used and should be at least once for 30th September and then quarterly thereafter 4. The profession supports planning information to ensure services are appropriate and accessible, but data shared must not be used for the performance management of GP Practices 5. In relation to GP appointments, there is an existing process around GP appointments (to be confirmed) led by NHSX SRO Dr Masood Nazir, GP data for planning must not replace this process 6. PAG noted that there should be a clear definition of the criteria by which out of area patients are identified by provider organisations. This is important because GP data from practices outside of the requesting CCG in the DARS application will flow 7. The need to ensure that organisations only use data for the purposes listed was discussed. PAG were assured by NHSD that the broader contractual framework clearly covered this requirement 8. PAG also noted that Article 9(2)(g) was used as the legal basis; PAG also noted that 9(2)(h) was considered as more appropriate 9. PAG will be informed by NHSD if there are any particular considerations around the processors involved.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Pam Soorma	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 15th July 2020

Application: DARS-NIC-384781-J8H2K-v0.2 **Organisation name: NHS Wakefield CCG** **Profession Advisory Group Agenda item: 3**
PAG supported the application, with the following comments: 10. IGARD's attention were drawn to the need for CCG's to have a transparency notice 11. CCGs should be asked to provide updates to RCGP and BMA via the dedicated PAG mailbox (gppr.profadvisorygroup@nhs.net) on how the data has been used and should be at least once for 30th September and then quarterly thereafter 12. The profession supports planning information to ensure services are appropriate and accessible, but data shared must not be used for the performance management of GP Practices 13. In relation to GP appointments, there is an existing process around GP appointments (to be confirmed) led by NHSX SRO Dr Masood Nazir, GP data for planning must not replace this process 14. PAG noted that there should be a clear definition of the criteria by which out of area patients are identified by provider organisations. This is important because GP data from practices outside of the requesting CCG in the DARS application will flow 15. The need to ensure that organisations only use data for the purposes listed was discussed. PAG were assured by NHSD that the broader contractual framework clearly covered this requirement 16. PAG also noted that Article 9(2)(g) was used as the legal basis; PAG also noted that 9(2)(h) was considered as more appropriate 17. PAG will be informed by NHSD if there are any particular considerations around the processors involved.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Pam Soorma	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 15th July 2020

Application: DARS-NIC-387358-H3Z2J-v0.2 **Organisation name: Birmingham and Solihull CCG** **Profession Advisory Group Agenda item: 2**
PAG supported the application, with the following comments: 18. IGARD's attention were drawn to the need for CCG's to have a transparency notice 19. CCGs should be asked to provide updates to RCGP and BMA via the dedicated PAG mailbox (gppr.profadvisorygroup@nhs.net) on how the data has been used and should be at least once for 30th September and then quarterly thereafter 20. The profession supports planning information to ensure services are appropriate and accessible, but data shared must not be used for the performance management of GP Practices 21. In relation to GP appointments, there is an existing process around GP appointments (to be confirmed) led by NHSX SRO Dr Masood Nazir, GP data for planning must not replace this process 22. PAG noted that there should be a clear definition of the criteria by which out of area patients are identified by provider organisations. This is important because GP data from practices outside of the requesting CCG in the DARS application will flow 23. The need to ensure that organisations only use data for the purposes listed was discussed. PAG were assured by NHSD that the broader contractual framework clearly covered this requirement 24. PAG also noted that Article 9(2)(g) was used as the legal basis; PAG also noted that 9(2)(h) was considered as more appropriate 25. PAG will be informed by NHSD if there are any particular considerations around the processors involved.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Pam Soorma	Secretariat	NHS Digital
Julian Costello	GP	RCGP

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 29th July 2020

Application: DARS-NIC-374190-D0N1M-v1.1 **Organisation name: NHS Digital** **Profession Advisory Group Agenda item: 2**
PAG suggested that evidence of the GenOMICC-GEL COVID being commissioned by the CMO/SAGE or prioritised by HDRUK is required to confirm the COPI basis. PAG suggested that the application make clear that the broader context at the start of the application was for context, and the para on p18 ("Over the next five years") was removed as not relevant. PAG noted the potential use of the data for risk scores (5d). If risk calculators or algorithms were to be generated from the data, this should be done in conjunction with MHRA. PAG have seen details in relation to the "Prior Principle" (SD19 within the application pack) and would ask GEL to include it within the commercial section of the application. PAG noted that members of the Forum are obliged to publish findings, and reinforced the view that all findings must be published. PAG suggested that the statement that individuals have given consent for commercial access on p21 could be removed, given that the basis for the application was not consent and instead COPI. PAG noted that the data is de-identified by Genomics England. PAG requested that the means of de-identification should be included within the DPIA as published. PAG noted that the application was significantly improved, and thanked Genomics England and DARS for their efforts. If the above points are addressed, PAG support this application for GP Data.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Garry Coleman	Associate Director of Data Access	NHS Digital
Anu Rao	GPC IT Policy Lead	BMA
Amir Mehrkar	GP, Clinical Researcher	RCGP
Julian Costello	GP	RCGP
Peter Short	GP	NHS Digital
Pam Soorma	Secretariat	NHS Digital

Appendix C

Independent Group Advising on the Release of Data (IGARD)

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

held via videoconference, Tuesday, 4 August 2020

In attendance (IGARD Members):	Prof. Nicola Fear (Specialist Academic Member)
	Kirsty Irvine (IGARD Lay Chair)
	Dr. Imran Khan (Special GP Member)
In attendance (NHS Digital):	Garry Coleman (DARS – Item 2.5)
	Cath Day (DARS – Item 2.2)
	Louise Dunn (DARS – item 2.5 & 2.6)
	Duncan Easton (DARS – Item 2.5)
	Collette Healey (DARS – item 2.1)
	Heather Pinches (DARS – item 2.1)
	Kimberley Watson (DARS – item 2.3 & 2.4)
	Vicki Williams (IGARD Secretariat)

2	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (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 Data Access Request Service (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:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising on COVID-19. Imran Khan noted a previous professional link with the Royal College of General Practitioners (RCGP) (NIC-381683-C9B4L) but noted no specific connection with the application or staff involved and it was agreed that this was not a conflict of interest
2.1	<u>COVID-19 Vaccine Trials (no NIC number available) / Permission to Contact</u> **Background:** This was an update to the discussion at the COVID-19 Response Meetings on the 23rd June and 7 July 2020, by way of an updated briefing paper and presentation of previous points raised, which was about the 'permission to contact' service for UK citizens and other current clinical trials which were ongoing as noted in both the UK Government's press briefings and associated news items on the BBC news website (or other news outlet website).

	NHS Digital noted that the '*sign up to be contacted for coronavirus vaccine studies service*' or Permission to Contact (PtC) Service had gone live on the 20 July 2020, and that the minimum viable product (MVP) had been updated to taken onboard previous observations made, including updating and publishing a privacy notice, more consistent use of language and providing more detailed information on the NHS.uk website about the coronavirus research. **IGARD Observations:** IGARD members noted that the updated briefing paper and presentation had been very helpful and suggested that the briefing paper be updated and circulated to IGARD members, and tabled at the next available IGARD business as usual meeting (BAU) meeting and before the first application for data. IGARD members noted previous comments made at the 7th July COVID-19 response meeting that these application(s) would not be suitable for the NHS Digital precedent route, given the potentially repercussive and high profile nature of the work being undertaken with the data. In addition, the executive summary of the briefing paper should be updated to reflect when it had been presented to a COVID-19 response meeting. IGARD members suggested that the briefing paper be updated to include information from the Data Protection Impact Assessment (DPIA) with regard to the fact that applicants' consent materials will have appropriate information with regard to any potential future data linkage with NHS Digital. IGARD members noted that for PtC applications, the default position should be an express statement in section 5 that the applicant cannot link data to data already held. Noting the NHS Digital DARS Standard for Data Minimisation, IGARD suggested that this would be a useful document for researchers when completing their applications for PtC data to ensure they were detailing the data minimisation efforts undertaken. IGARD members reiterated their previous comments from the 7th July meeting that moving forward, NHS Digital should proactively work with the vaccine trial organisations to review draft consent documentation and before they request data from NHS Digital to ensure that the downstream work progresses smoothly. IGARD members noted that due to the fact that there was no linkage permitted for this unique data asset, that there may be distress caused to surviving family members should researchers or NHS Digital contact those who had volunteered for PtC, but had subsequently died. Although noting this was raised as a risk on the DPIA, IGARD members suggested that NHS Digital seek further guidance from the NHS Digital Caldicott Guardian, since there appeared to be a strong public interest argument in favour of providing a regular list cleaning service for this data asset. IGARD also suggested that this risk assessment and analysis in the DPIA be brought over into the briefing paper so that IGARD members were aware of the consideration that had already been given to the risk of contacting deceased PtC volunteers. **Subsequent to the meeting:** IGARD members raised an additional point with regard to Amazon Web Services who were listed as a Data Processor in the briefing note and queried, from a GDPR transparency perspective, whether that had been noted in the published Privacy Notice or other public-facing materials.
2.2	<u>NIC-377644-X9J4P University of Sheffield</u> **Background:** This was a verbal update about a new application for the Pandemic Respiratory Infection Emergency System Triage (PRIEST) Study and has been marked as essential

	COVID-19 related study by the National Institute for Health Research (NIHR). The data requested is Civil Registration (deaths), Demographics, Hospital Episode Statistics (HES) Admitted Patient Care (APC), Emergency Care Data Set (ECDS), HES Critical Care (CC) and GPES Data for Pandemic Planning and Research (GDPPR). The aim of the funded project is to evaluate and optimise the triage of people using the emergency care system (111, 999 calls, ambulance conveyance, or hospital emergency department). NHS Digital noted that a draft application and supporting documentation was available, but had not been provided for review. The following observations are made on the basis of the verbal briefing only **IGARD Observations:** IGARD members queried the timeframe for the PRIEST Study and were informed by NHS Digital that the study had reached its cohort target of 20,000 by late May 2020. IGARD members queried how the study would use the GDPPR data retrospectively and what the GDPPR data was being used for, in addition to the other datasets requested and that the additional value gained from the GDPPR dataset should be explicitly reflected within the application and supporting documentation. IGARD noted that DARS were waiting for feedback from NHS Digital's information governance (IG) directorate with regard to the legal basis for the dissemination of GDPPR data under Health Service (Control of Patient Information Regulations) 2002 (COPI). IGARD members noted the method of triaging, but were unclear how the study would pick up those triaged via the GP out of hours service, since the data they were potentially requesting did not contain that particular data field, and suggested that applicant may wish to apply for other data sets, such as Public Health England's (PHE) Second Generation Surveillance System (SGSS) data. IGARD were unclear why historical data for patients was to be disseminated under this application and asked that a clear justification for the number of data years be provided in section 5 (Purpose / Methods / Outputs) and that this justification also aligned, as may be necessary, with the Health Research Authority Confidential Advisory Group (HRA CAG) s251 support, which had already been obtained for this study.
2.3	<u>NIC-393650-B7J6F Department of Health (DoH) / Ipsos Market and Opinion Research International (MORI)</u> **Background:** This was an urgent COVID-19 application from the Department of Health and Imperial College London for record level identifiable demographic data to flow to Ipsos MORI to support the REACT1 study (Real-time Assessment of Community Transmission 1). This application is to support three waves of data being supplied to support 4-6 of the antigen testing study, with the surveys being completed in August, September and October 2020. In each wave to achieve the required sample size of 150,000, the names and demographic details of 750,000 individuals aged 5 years and above would be requested. NHS Digital had provided one drop of data in April 2020 under a letter of release from NHS Digital's Information Governance (IG) directorate. The REACT2 study had previously been considered at the COVID-19 response meeting on the 14th July 2020

	IGARD Observations: IGARD members noted that supporting document (SD) 8, the NHS Digital IG email approval for release 28 April 2020, specifically stated "…*the data being shared is demographic data only therefore not confidential patient information*…" however the application noted in section 1 (Abstract) and section 5(a) (Objective for Processing) that "…*legal basis for identifiable data to flow is under Regulation 3(4) of the Health Service (Control of Patient Information Regulations) 2002 (COPI)…*", in section 3 (Common Law Duty of Confidentiality) that "*the common law duty of confidentiality is addressed by: statutory exception to flow confidential data without consent*" and in section 3(b) (Additional Data Access Requested) "…*Dissemination: COPI Reg 2020*…" IGARD asked that clarification be sought of what the legal basis was, since there appeared to be a supporting documentation missing detailing this key information (and, in particular, if there was any information available as to why the legal basis appeared to have changed since the initial data flow). IGARD members noted that section 2(a) (Processing Locations) referenced an Ipsos MORI office in Germany and suggested that this processing location should be explicitly detailed in the applicant's privacy notice. Dependent on the legal basis relied upon, IGARD also suggested that the application set out how Ipsos MORI, as a processor of confidential patient information, satisfied the requirement in Regulation 7(2) COPI and whether or not reliance on COPI meant there was any geographical restriction on confidential patient information being transferred to Ipsos MORI in Germany. IGARD noted that the UK Government's stay at home guidance for households with possible or confirmed COVID-19 infection stated that you must self-isolate for at least 10 days from when symptoms started and arrange to have a test to see if you have COVID-19, and suggested the application and any supporting documentation be updated to reflect this new guidance. Noting NHS Digital's DARS Standard for Data Minimisation, IGARD members suggested for transparency and for the benefit of informing the public, that the research undertaken within this application should clearly outline how it is distinct / novel and adding to the similar work already being undertaken by Public Health England (PHE), or other similar organisations. In addition, IGARD members suggested that the SD's clearly reflected that '*date of birth*' was **not** flowing, since the application was clear that only the month and year of birth were required.
2.4	<u>Virtual Ward (No NIC number available)</u> **Background:** This was a verbal update about evidence that patients are presenting late to hospital because of stay at home messages and perception that there is no treatment available and that this could have a negative impact on outcomes. There are a number of initiatives across England looking at Pulse Oximetry in the home (including residential and care homes) for patients to measure their own oxygen levels. Currently three pilot sites have been approved in London, Slough and South Tees, with Liverpool and South Central Ambulance as two potential initiatives to be included. **IGARD Observations:** Noting that an application was due to be presented to the IGARD business as usual (BAU) meeting on Thursday, 13 August, IGARD members suggested that DARS ensure they had the

	appropriate NHS Digital Information Governance (IG) directorate written advice for the collection and dissemination of the developing data set. Although IGARD members welcomed the brief overview but suggested that a protocol be provided with the application as a supporting document. IGARD noted that for any specific individuals named in the project that conformation be provided that they were a substantive employee of the Data Controller or they had a honorary contract in place (which meets NHS Digital's DARS usual standard for honorary contracts). IGARD members suggested that the application be updated throughout to clearly delineate between the COVID-19 work and the proposed "wider use", particularly if there was a different legal basis for each distinct work package. In addition, they suggested that if the COVID-19 work was urgent that consideration should be given by DARS to the first application just containing that specific project, with amendments at a later time to encompass the "wider work".
2.5	NIC-384608-R6R6K NHS England (Skipton House) **Background:** this was a verbal update to the application which was due to be presented to the business as usual (BAU) meeting of IGARD on Thursday, 6th August 2020 The application had been previously discussed at the COVID-19 response meeting on the 21st July 2020 and had been previously deferred at the IGARD BAU meeting on Thursday 23rd July 2020. NHS Digital noted that following its previous presentation at PAG and IGARD, the application had been significantly re-written. **IGARD Observations:** IGARD members noted that the application had been significantly re-written and was to be presented to the IGARD BAU Meeting on Thursday, 6th August 2020, and that it was to be presented following a review by the Profession Advisory Group (PAG) on Wednesday, with a copy of this minute extract appended to IGARD's published minutes IGARD Members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting on Thursday and thanked NHS Digital for their verbal update.
2.6	NIC-381683-C9B4L Public Health England (PHE) / University of Oxford / University of Surrey **Background:** this was an update to the application presented to the COVID-19 response meetings on the 30th June, 9th June ad 26th May 2020. This application referred to the three observational studies and NHS Digital noted that these studies have received Health Data Research UK (HDRUK) and NHS Digital prioritisation. PHE had commissioned the Royal College of General Practitioners (RCGP) Research Surveillance Centre (RSC) to incorporate the monitoring of COVID-19 into its virology surveillance scheme and a vital part of that work has bene to monitor the number of suspected COVID-19 cases in the community in a timely way. NHS Digital noted that they had updated part of the application in line with previous observations made, but that more work was required with regard to the Data Controller / Data Processor and following information received from the applicant.

	IGARD Observations: NHS Digital noted that since last presented they had received feedback from NHS Digital's information governance (IG) directorate and that the applicant was relying on PHE's Health Service (Control of Patient Information Regulations) 2002 (COPI) notice. IGARD members noted the update and in addition to the IG written confirmation forming part of the suite of supporting documentation, plus uploaded to the Customer Relationship Management (CRM) system, asked that a copy of PHE's COPI notice be provided and uploaded to CRM to support the legal basis statement in section 1 (Abstract). NHS Digital noted that the applicant had provided further detail with regard to the roles of the Data Controllers / Data Processors, however IGARD members reiterated their comments from the 30th June meeting that the three Data Controllers listed (PHE, University of Surrey and RCGP) be clearly articulated in section 5 (Purpose / Methods / Outputs) in terms of their role and remit, and in addition that the role of University of Oxford be clearly articulated in section 5, plus any other part of the application that required an update. IGARD members reiterated their comment from the 30th June meeting, and noting the applicant had provided an update, queried whether or not any further support might be available. IGARD members noted that the applicant had provided a data flow diagram, as suggested at the 30th June meeting, and suggested that applicant work with NHS Digital to refine the information further to ensure consistent use of language terminology and update the legal basis for each data flow. IGARD members noted in section 5(a) (Objective for Processing) that the applicant was monitoring the number of cases in the community but queried why they were not asking for PHE's Second Generation Surveillance System (SGSS) data, and that further consideration be given to the fields it contained. In addition, IGARD members noted reference to mortality and Hospital Episode Statistics (HES) data, however since they were not requesting this data from NHS Digital, asked that clarification re sought as to whether any linkages were happening outside of NHS Digital and to clarify where this additional data was coming from. IGARD noted reference to a 'protocol' and if available this should be provided as part of the supporting documentation pack and a copy uploaded to NHS Digital's CRM system. IGARD noted the efforts undertaken by the applicant to meet NHS Digital's Standard for privacy notices.
3.	AOB There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.