Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 9 December 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Garry Coleman	Associate Director / Senior Information Risk Owner (SIRO) (Item 4.1)
Dave Cronin	Data Access Request Service (DARS) (Item 4.1)
Faris Dean	Data Access Request Service (DARS) (Observer: items 2 – 4)
Louise Dunn	Data Access Request Service (DARS) (Items 3.1 – 3.2)
Laura Evans	DigiTrials (Observer: 3.3 – 3.4)
Liz Gaffney	Head of Data Access, Data Access Request Service (DARS) (Item 7.1)
Dan Goodwin	Data Access Request Service (DARS) (Observer: item 3.1)
James Gray	Data Access Request Service (DARS) (Item 3.4)
Paul Hague	Data Access Request Service (DARS) (seconded from PTE) (Observer: items 3.1 – 3.4)
Karen Myers	IGARD Secretariat
Frances Perry	DigiTrials (Item 3.3 – 3.4)
Anna Weaver	Data Access Request Service (DARS) (Observer: item 3.6)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 2nd December 2021 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	**Briefing Notes**
2.1	<u>National Cancer Registration and Analysis Service (NCRAS) and the National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) – Briefing Papers (Presenters: Louise Dunn / Liz Gaffney)</u> The briefing papers were to inform IGARD, that the Secretary of State for Health and Social Care has directed NHS Digital to establish and operate a system for the collection and analysis of information in respect of the: • Individuals diagnosed with cancer, treated for cancer, suspected of having cancer, or with certain conditions that may lead to cancer; and • Individuals with confirmed, suspected or high genetic or other risk of a congenital anomaly or rare disease; and relevant family members of such individuals. The data was previously processed by PHE in discharge of the Secretary of State's public health functions under section 2B and under section 251 of the National Health Service Act 2006 (Section 251). • PHE processed the cancer data through the **National Cancer Registration and Analysis Service (NCRAS)**. The data was collected and processed without patient consent under Section 251 (Ref: PIAG 03(a)/2001) and regulation 2 of the Health Service (Control of Patient Information) Regulations 2002 (COPI) (Medical purposes related to the diagnosis or treatment of neoplasia). • PHE processed data about congenital anomalies and rare diseases through the **National Congenital Anomaly and Rare Disease Registration Service (NCARDRS)**. The data was processed without patient consent under Section 251 and Regulation 5 of COPI (General). Collectively, the registries are known as the **National Disease Registries (NDR)**. Responsibility for operating and maintaining the NDR was transferred to NHS Digital under the NDR Directions 2021, when PHE ceased to exist on the 1 October 2021. **NCRAS** is responsible for population-based cancer registration in England. The NCRAS collects information about individuals diagnosed or treated for cancer in England and individuals in England suspected of having cancer, with a high genetic risk of cancer, or with certain conditions that may lead to cancer. The collection aims to provide the following benefits to patients and the public: • increase prevention and early diagnosis of cancer; • improve the management of NHS cancer services;

	• improve NHS cancer treatment and care; • improve patient outcomes, including better quality of life and longer survival. Once an individual is registered, the service will continue to receive information about their cancer whenever they are seen or treated for cancer. Data collection continues up to and including details of an individual's death. **NCARDRS** collects information about individuals with confirmed, suspected or at high genetic or other risk of congenital anomalies and inherited or rare diseases in England; and their relevant family members. This includes data pertaining to affected fetuses. The processing aims to understand the prevalence of congenital anomalies and rare diseases in England and how outcomes for people with these conditions are affected by gender, ethnicity, disease type, and geographic region. **Outcome:** IGARD welcomed the briefing paper and made the following high-level comments: 1. IGARD suggested that NHS Digital adopt the previous ethics review requirement for research from the ODR system. As a result applicants applying for these datasets, even if applying for pseudonymised datasets, would require local or institutional ethics support. If they do not have a standing ethics committee, then IGARD suggested that a memo of support from their Caldicott Guardian would likely suffice. If they have neither then IGARD noted that they would need to discuss what was appropriate on a case-by-case basis. 2. In respect of the EMT Briefing Paper: a) IGARD noted that the sensitive field, which is currently not ticked, should be marked as there is death registration data (which according to the footnote within the briefing paper, **is** a sensitive data field). b) IGARD asked that the briefing paper was updated with the definition of 'medical purpose' as defined in section 251(12) of the National Health Service Act 2006, rather than The Health Service (Control of Patient Information) Regulations 2002, as advised out of committee via an email forwarded from PTE. 3. In respect of transparency: a) IGARD noted concern regarding how members of the cohorts could ever discover they were part of the cohort. IGARD suggested that the transparency was uplifted to a sufficient standard to ensure cohort members could identify if they are included. b) IGARD advised that they would like to see a relevant DPIA/s in advance of any applications being submitted to an IGARD BAU for review. c) IGARD noted that members of the public would be directed through various websites, including the gov.uk website to a PHE email address that no longer existed and asked that this was updated as a matter of urgency. 4. IGARD noted the involvement of the Patient Information Forum, and supported this approach and suggested that NHS Digital continue working with the Forum. IGARD welcomed the draft briefing paper and looked forward to receiving the updated briefing paper **and** any relevant supporting documents, at a future meeting alongside a first of type application as a supporting document, as per usual practice.
2.2	<u>Relying on consultees as a basis for participating in research where an individual lacks capacity to consent – Briefing Paper (Presenter: Louise Dunn)</u>

	When researchers are attempting to carry out research but there are participants who lack the mental capacity to provide consent, the use of a consultee may be an appropriate gateway to include those participants. Under sections 30 to 33 of the Mental Capacity Act 2005 ("MCA"), the use of a consultee provides an alternative basis to the common law duty of confidentiality for the inclusion of a participant who lacks the ability to provide consent to take part in some forms of research. This does not include clinical trials. It must be noted however, that this consultee does not provide consent on behalf of the participant but rather advice. It is a statutory authority on the condition that the requirements of sections 30 to 33 of the MCA are met. The most appropriate lawful basis for NHS Digital to rely upon concerning the dissemination of data is section 261(5)(d) of the Health and Social Care Act 2012. This section would be used on the basis that if researchers can satisfy the requirements of Article 6(1)(e) UK GDPR, then this could be relied upon in regard to section 261(5)(d). To support the DARS team when reviewing applications regarding research which may include persons who lack capacity to give consent, the PTE team created a 'Decision making workflow for DARS applications wishing to rely on the MCA Consultee Process' table. This was produced to provide a checklist for DARS, setting out when the MCA Consultee Process applies and the statutory requirements that must be satisfied for this to relied upon. **Outcome:** IGARD welcomed the briefing paper and made the following high-level comments: 1. IGARD noted the inclusion of a flowchart, and suggested that a large proportion of this chart, could be substituted with appropriate HRA REC support. IGARD noted it was the responsibility of REC to undertake the assessments as discussed. 2. IGARD noted the advice received from NHS Digital and suggested that a further discussion with regards to any perceived or actual barriers to the dissemination of data, where legitimate interests is relied on as a UK GDPR legal basis, be discussed at a future IGARD BAU meeting, early in the New Year. 3. IGARD recommended that NHS Digital discussed the requirement for research to be connected with an impairing condition with the Health Research Authority, because IGARD had seen applications where the research did not seem to be so connected.
3	**Data Applications**
3.1	University College London (UCL): Linkage of NHS Digital data to young people with perinatal HIV, to monitor cancers and deaths. (Presenter: Frances Perry) NIC-368477-C9Q1X-v0.9 **Application:** This was a new application for pseudonymised Cancer Registration Data, Civil Registration (Deaths) and Demographics data. The purpose is for the 'Collaborative HIV Paediatric Study' (CHIPS)+, which includes young people, aged 15 years and upwards, from the original CHIPS, a national cohort study of children living with HIV in the UK. The aim is to provide evidence on health outcomes in early adulthood and will provide the foundation for long-term monitoring. Within the cohort the study team have estimated the risks of cancers and deaths in paediatric care, however, there are no comprehensive estimates of incidence of cancers and deaths in adult care, therefore the study team have request to link NHS Digital data to the cohort of CHIPS+ participants. The objectives of the CHIPS+ study is: **1)** to consent participants with perinatal human immunodeficiency virus (PHIV), aged 15 years and over into a new perinatal HIV adult cohort for CHIPS+ and create a dataset containing life course (paediatric and adult) disease and

	treatment history; **2)** to estimate prevalence / incidence of engagement in care and key health outcomes pre-and 1-5 years post-transition, overall and by clinic type. The consented cohort consist of 750 participants aged 15 years and upwards. **Discussion:** IGARD noted and commended NHS Digital on the quality of the information provided within the application, which supported the review by Members. IGARD also noted the importance of the work being carried out in this study. IGARD noted that at the IGARD business as usual (BAU) meeting on the 5th August 2021, NIC-148128-815J1 (UCL) had been reviewed by IGARD and recommended for approval. The application was for 'The National Mother and Child Cohort' which was established in 1995 as an extension to the National Surveillance of HIV in Pregnancy and Childhood (NSHPC) that collected data on pregnancies in women living with HIV and their infants. Since 2018 the NSHPC has been absorbed by the Integrated Screening Outcomes Surveillance Service (ISOSS) based at UCL. Monitoring of the cohort would provide long term follow up of the cancer and death registration of children born to women living with HIV. ISOSS had collected data on approximately 25,000 pregnancies and their outcome since 1995 with the aim of identifying any significant health inequalities with a view of informing policies to remove barriers to this population's survival. IGARD queried if the study team for this application was aware of the larger surveillance project; and were advised by NHS Digital that the same study team were leading on both NIC-368477-C9Q1X and NIC-148128-815J1. IGARD noted the verbal update from NHS Digital, and asked that for transparency, section 5(a) (Objective for Processing) was updated with a brief overview of the larger surveillance project (NIC-148128-815J1), for example with a relevant web link. IGARD confirmed that they had reviewed the consent materials as part of the review for NIC-148128-815J1 on the 5th August 2021, and were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. IGARD noted in section 1 (Abstract) that there were ongoing discussions with NHS Digital's Privacy, Transparency and Ethics (PTE) in respect of whether the National Data Opt-out (NDO) should be applied, for those members of the cohort who were recruited by consultee advice. IGARD queried if consultee advice could be relied upon in this factual scenario, noting that the research would need to concern a qualifying *"impairing condition"* under the Mental Capacity Act 2005 for consultee advice to be provided for a participant. IGARD asked that the applicant provided written confirmation that the applicant had contacted the Health Research Authority (HRA) / Research Ethics Committee (REC) to check with them whether consultee advice can be relied upon in this factual scenario. In addition, IGARD asked that following the applicant's discussion with HRA / REC, that any necessary changes were made to the application, as may be requested; and that the written confirmation from HRA / REC was uploaded to NHS Digitals CRM system, for future reference. IGARD noted the narrative in section 3(c) (Patient Objections) *"Consent (those participants who have been recruited under a consultee will have National Data Opt Out Applied)."* was removed as it was not relevant. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt

	of data; in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted that section 3(b) incorrectly stated that the Cancer Registration data was *"pseudonymised",* and asked that this was updated to correctly reflect that it was *"identifiable".* IGARD queried the statement in section 5(b) (Processing Activities) that stated *"…UCL is not permitted to re-identify individuals under this agreement."*, and noting that UCL were permitted to re-identify individuals, asked that this incorrect statement was removed. IGARD noted the statement in section 5(b) in respect of the HES analysis guide *"cell values from 1 to 7 (inclusive) are suppressed at a **local** level to prevent possible identification of individuals…"*; and asked the reference to *"local"* was replaced with *"sub-national"*. IGARD noted that the application was silent on the steering committee activities, and queried if the CHIPS+ steering committee was active and whether or not it had patient and public involvement and engagement (PPIE), as set out in supporting document 1.0, the protocol. NHS Digital noted that the applicant had confirmed that the CHIPS+ steering committee was active whilst the study was open and recruiting; and that there were three patient representatives on the steering committee, who were all women living with HIV and also parents, who attended the steering committee meetings and helped with the design of the patient leaflet about CHIPS and CHIPS+. In addition, there was also input from the Youth Trials Board (YTB) in the development of the leaflet. The YTB is part of the Children's HIV Association (CHIVA) and is made up of a group of young people living with HIV who have some background on what clinical trials and studies are; and ensure young people have a meaningful and influential involvement in how clinical trials are designed, developed and delivered. IGARD noted the update from NHS Digital, and asked that for transparency, section 5 (Purpose / Methods / Outputs) was updated with further details of the early PPIE. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" or "it can…", and instead use a form of words such as "*it is hoped*…" IGARD noted the references within section 5(a) to *"delivery"* and suggested that "*delivery*" was replaced with the term *"birth"*. Separate to this application, NHS Digital noted that they would bring to a future IGARD BAU meeting a discussion item with regard to delivery / birth since the terms may mean different things with regard to the data collected / disseminated. IGARD welcomed the future discussion. IGARD noted that section 5(a) appeared to refer to "*PHIV"* being consented, for example *"To consent PHIV aged 15 years and over…"*; and asked that this was reviewed and any references to the condition being consented were removed, as it was the individual who was being consented not the disease. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the consultee advice: a) To provide written confirmation that the applicant has contacted HRA / REC, to check with them whether consultee advice can be relied upon in this factual scenario; specifically whether there is a qualifying *"impairing condition"* that falls under the Mental Capacity Act 2005. b) Following discussion with HRA / REC, to make any necessary changes, as may be requested, to the application.

	c) To upload the written confirmation from HRA / REC to NHS Digitals CRM system, for future reference. The following amendments were requested: 1. To update section 5(a) with a brief overview of the larger surveillance project (NIC-148128-815J1), for example with a relevant web link. 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 3. To update section 3(b) to correctly reflect that the Cancer Registration data is *"identifiable"* and not *"pseudonymised"*. 4. With reference to the HES analysis guide in section 5(b), to replace *"local"* with *"sub-national"*. 5. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 6. To remove the narrative in section 3(c) in respect of the NDO as this is not relevant. 7. In respect of the language in section 5(a): a) To replace the reference to *"delivery"* in section 5(a) with *"birth"*. b) To review section 5(a) to remove any reference to *"PHIV"* being consented, as it is the individual who is being consented not the disease. 8. To remove the incorrect statement in section 5(b) *"UCL is not permitted to re-identify individuals"*. 9. To update section 5 with further details of any early PPIE (as per the verbal update from NHS Digital). It was agreed the conditions would be approved out of committee (OOC) by the IGARD Chair.
3.2	<u>University Hospital Southampton NHS FT: Phase I Vaccine Study of pEVAC-PS (Presenters: Frances Perry / James Gray) NIC-594129-R0M3W-v0.2</u> **Application:** This was a new application for identifiable Permission to Contact (PtC) data; for the purpose of a vaccine trial study, 'A phase I safety, immunogenicity and dose escalation study of the candidate pan-Sarbeco Coronavirus vaccine pEVAC-PS in SARS-CoV-2 immunised UK healthy adult volunteers'. The study will use an established needleless vaccine delivery technology to assess the optimal dose required to trigger patients' cells to produce the antigens, be recognised by participants immune systems and boost antibody titres that will induce durable protection against SARS-CoV-2 and SARS-CoV. Combined with needleless and powerless (no electrical source required) delivery, this platform offers a safe, widely deployable pan-Sarbeco Coronavirus vaccine for large scale immunisation programmes. The aim is to recruit a total of 36 participants. The initial mailout will aim for around four / five times the number of potential participants to be recruited and therefore the estimate is for around 180 individuals to be contacted via the Permission to Contact (PtC) Service. The PtC Service is where members of the public can register their details and give their permission to be contacted by researchers working on National Institute of Health Research (NIHR) approved UK coronavirus vaccine trials about participating in those trials. This PtC Service, which is called "Sign Up to be Contacted about Coronavirus Vaccine Studies" on the nhs.uk website was launched as a national service on 20th July 2020. NHS Digital advised IGARD that following submission of the application for IGARD review, it had been noted that the territory of use in section 2(c) (Territory of Use) would need updating

	from *"England and Wales"* to the *"UK"*, noting that data may be sent to NHS Digital from Scotland / Northern Ireland. **Discussion:** IGARD welcomed the application and noted the importance of the ground-breaking study. IGARD noted the verbal update from NHS Digital in respect of the amendment to section 1(c) (Data Processor(s)) to reflect that the territory of use was the *"UK"* and not *"England and Wales"*. IGARD advised NHS Digital that the review undertaken by members, was for access to the PtC data only, and that there had **not** been an in-depth review of the consent materials. IGARD noted that they would be happy to support the applicant / NHS Digital with this at a future meeting, if required. IGARD did however make some comments / suggestions in respect of transparency with the cohort. IGARD noted the information provided within supporting document 4.1, version 2.1 of the participation information sheet; and strongly suggested that the study team were transparent with the potential participants that were contacted, that, by participating in the research, they would be unable to receive a COVID-19 booster vaccine. In addition, IGARD suggested that the narrative outlining who was eligible for a COVID-19 booster vaccine was updated to reflect the most recent guidance in operation, and that it was clear that it was correct at the time of writing, noting that the eligibility rules were subject to change at short notice. IGARD strongly suggested that NHS Digital engaged with the applicant to ensure their consent materials, included, amongst other key aspects, narrative around potential long-term follow-up, the sharing of data with NHS Digital, and other national bodies or researchers or international research institutions, manufacturers of medicines or devices, international regulatory authorities etc; should clearly describe the type of data that may be gathered, and to describe any possible linkages, as well as addressing the UK General Data Protection Regulation (UK GDPR) transparency requirements, for example listing Data Processors etc. IGARD noted that there were a number of excluded groups, as would be expected in a phase I trial, however queried what procedure(s) were in place to address how these excluded groups would be included in the research in the future. IGARD also suggested that as part of the research development the applicant could complete an Equality and Health Inequalities Impact Assessment. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated that there was *"no"* commercial purpose; however, noting the involvement of a commercial organisation within the supporting documents; asked that section 5(e) was updated with a detailed description of any commercial purpose / benefit of the study for which the PtC cohort was being utilised; and in line with NHS Digital's DARS Standard for Commercial Purpose. In addition, IGARD asked that section 5(a) (Objective for Processing) was also updated with a brief summary of all of the commercial parties involved and any commercial aspect of the underlying study of which the Permission to Contact cohort will form part of; in line with NHS Digital's DARS Standard for Commercial Purpose and NHS Digital's DARS Standard for Objective for Processing. IGARD noted a number technical terms in section 5 (Purpose / Methods / Outputs), and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure technical terms were explained in a manner suitable for a lay audience, for example *"DNA plasmid expression vector pEVAC"*.

	Outcome: recommendation to approve The following amendments were requested: 1. To update section (1c) to reflect that the territory of use will be *"UK"* and not *"England and Wales"* (as per the verbal update from NHS Digital). 2. To update section 5(d) to use a form of wording such as "*hopefully",* rather than "*it will…*". 3. To update section 5, to ensure that all technical terms are explained in a manner suitable for a lay audience, for example *"DNA plasmid expression vector pEVAC"*. 4. In respect of the commercial purpose: a) To update section 5(e) with a detailed description of any commercial purpose / benefit of the study for which the Permission to Contact cohort is being utilised; and in line with NHS Digital's DARS Standard for Commercial Purpose b) To provide a brief summary in section 5(a) of all of the commercial parties involved and any commercial aspect of the underlying study of which the Permission to Contact cohort will form part of. The following advice was given: 1. IGARD strongly suggested that the study team were transparent to the potential participants that are contacted, that by participating in the research, they will be unable to receive a COVID-19 booster vaccine. In addition, IGARD suggested that the narrative outlining who is eligible for a COVID-19 booster vaccine is updated to reflect the most recent guidance in operation, and that it is clear that it is correct at the time of writing (noting the eligibility rules are subject to change at short notice). 2. IGARD noted that there were a number of excluded groups, as would be expected in a phase I trial, however queried what procedure were in place to address how the excluded groups will be included in the research in the future. IGARD also suggested that as part of the research development the applicant could complete an Equality and Health Inequalities Impact Assessment. 3. IGARD strongly suggested that NHS Digital engage with the applicant to ensure their consent materials, include (amongst other key aspects) narrative around potential long-term follow-up, the sharing of data with NHS Digital (and other national bodies or researchers or international research institutions, manufacturers of medicines or devices, international regulatory authorities etc) to clearly describe the type of data that may be gathered, and to describe any possible linkages, as well as addressing UK GDPR transparency requirements (for example listing data processors etc).
3.3	London School of Hygiene and Tropical Medicine: Impact of Community Perinatal Mental Health Teams on mental health and birth outcomes (The ESMI-II study) (Presenter: Charlotte Skinner) NIC-376141-W5D3L-v0.9 **Application:** This was a new application for pseudonymised Bridge file: Hospital Episode Statistics (HES) to Mental Health Minimum Data Set (MHMDS), Civil Registration (Deaths) Secondary Care Cut, HES Admitted Patient Care (HES APC), HES:Civil Registration (Deaths) bridge, Improving Access to Psychological Therapies Data Set (IAPT), Mental Health and Learning Disabilities Data Set (MHLDDS) AND Mental Health Services Data Set (MHSDS). Perinatal mental health (PMH) problems (i.e., Mental Health problems occurring during pregnancy or the first year after childbirth) can have a severe impact on women and their babies. Severe mental health problems can be associated with significant impairment in social and personal functioning, which might affect the woman's ability to care for herself and her

	child. Psychiatric causes of maternal death, particularly suicide, continue to be a significant cause of maternal mortality in the UK. This purpose of the application is for Work Package 4 of the 'Effectiveness and Cost Effectiveness of Community Perinatal Mental Health ServIces' (ESMI-II); specifically to *"Investigate the effectiveness of community perinatal mental health teams (CPMHT) in improving access, outcomes, and preventing relapse, and thus reducing cost, using national NHS datasets"*. Data is required for a cohort of women who have given birth between the 1st April 2014 and 31st March 2020, and who had an episode of a secondary mental health care episode from the 1st April 2006. **Discussion:** IGARD noted that the cohort was only those women who had been diagnosed with PMH problems and also had pre-existing severe mental health disorders, i.e. if they had contact with secondary care mental health services in the NHS from 2006 up to the start of pregnancy; and advised that they would be supportive of additional flows of data to capture **all** women with diagnosed PMH problems, including those with no previous history of mental health illness. IGARD queried the statement in section 3(b) (Additional Data Access Requested) that *"GDPR does not apply to data solely relating to deceased individuals"*, however, noting that the status of those patients that are still alive would be revealed, asked that, this was updated to include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; if in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD noted that the application was silent on the cohort numbers, and asked that in line with NHS Digital's DARS Standard for Data minimisation, section 3(b) and section 5(b) (Processing Activities) were updated with an indicative cohort size. IGARD noted that section 5(a) (Objective for Processing)was not clear on the data minimization efforts undertaken, and asked that this public facing section, that forms NHS Digital's data uses register, was updated with a brief explanation; in line with NHS Digital's DARS Standard for Data minimisation and NHS Digital DARS Standard for Objective for Processing. IGARD queried the statement in section 7 (Ethics Approval) *"Ethics approval is not required because the request does not include the flow of confidential data."*; and asked that this was updated to correctly reflect that there was local institutional ethics approval for the study. IGARD noted the reference to patient and public involvement and engagement (PPIE) in the application, however suggested that the applicant may wish to consider involving the relevant public and patient groups as early as possible, and not just at the end of the study; in line with HRA guidance on Public Involvement. IGARD also asked that if there was any earlier PPIE, section 5 (Purpose / Methods / Outputs) was updated with further information. IGARD noted the reference to the '*HES Analysis Guide*' in section 5(b), and asked that this public facing section, which forms NHS Digital's data uses register, was updated with a summary of the HES Analysis Guide, suitable for a lay reader. IGARD also asked that the update specifically referred to *"sub-national" as opposed to "local" , for example "suppressed at a **local** level".*

	IGARD noted the references in section 5(a) to *"will answer"*, for example, *"…the key research question ESMI-II will answer is if CPMHT is effective…"*; and asked that this was update to state that it *"will address"*. IGARD noted the references within section 5(a) to *"delivery"* and suggested that the word "*delivery*" was replaced with the term *"birth"*. Separate to this application, NHS Digital noted that they would bring to a future IGARD BAU meeting a discussion item with regard to delivery / birth since the terms may mean different things with regard to the data collected / disseminated. IGARD welcomed the future discussion. IGARD noted the references throughout section 5(a) to *"mental health disorder"*, and noting that section 5 formed NHS Digital's data uses register, asked that this was updated, with an alternative, more sensitive term, such as *"mental health condition"* or *"mental ill health"*. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…" **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this accords with the latest advice from PTE. 2. To update section 3(b) and 5(a) with an indicative size of the cohort. 3. To update section 5(a) with a brief explanation of the data minimisation efforts. 4. In respect of the language in section 5(a): a) To update the reference in section 5(a) from the key research question *"will answer"* to *"will address"*. b) To replace the reference to mode of *"delivery"* in section 5(a) with *"birth"*. c) To update section 5(a), to amend the references from *"mental health disorder"* to an alternative such as *"mental health condition"* or "*mental ill health"*. 5. To update section 5 with further details of any early PPIE. 6. In respect of the HES Analysis Guide referenced in section 5(b): a) To provide a summary of the HES Analysis Guide referenced in section 5(b), suitable for a lay reader. b) With reference to the HES analysis guide in section 5(b), to ensure reference is made to *"sub-national"* as opposed to *"local"*. 7. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will*…". 8. To update section 7 to reflect that there is local institutional ethics approval for the study. The following advice was given: 1. IGARD noted the reference to PPIE in the application, however suggested that the applicant may wish to consider involving the relevant public and patient groups as early as possible, and not just at the end of the study; in line with HRA guidance on Public Involvement. 2. IGARD advised that they would be supportive of additional flows of data to capture **all** women with diagnosed PMH, who have no history of mental health illness.

3.4	University of Cambridge: MR598 - UK Study of the families of Ataxia Telangiectasia Patients (Presenter: Dave Cronin) NIC-148129-FK1JJ-v3.5 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report, MRIS - Members and Postings Report. It was also an amendment to **1)** add University of Birmingham as joint Data Controller; and **2)** add identifiable Cancer Registration Data, Civil Registration (Deaths) and Demographics data. The purpose is for a study which seeks to determine whether carriers of ATM (Ataxia Telangiectasia, Mutated) have an increased risk of developing cancer. The study began in 1998 and recruited the parents of children identified as carrying ATM as participants; at that time, there were 100 families with ATM. The parents of patients with ATM were identified from the AT-Society Register and their GPs were contacted by the research team to seek permission to contact the parents. For parents of children not on the AT-Register, the researchers contacted both the referring clinician and then the GP for permission to contact the parent. Both groups of parents were then contacted by the researchers and their participation proceeded on a consented basis. Patients with ATM were not contacted unless neither parent could be contacted, the patient was over 18 years of age, and the GP gave consent for the contact. In 2003, the University of Cambridge securely transferred the name, date of birth, address and sex of individuals in the cohort to the Office of National Statistics (ONS) to confirm details on cancer diagnoses and causes of death that were already held on these individuals. The individuals were also flagged on the ONS central register so that the researchers could be informed of any future cancers or deaths. Information was transferred from ONS to the University of Cambridge at regular intervals. The flagging service subsequently transferred to NHS Digital. The University of Cambridge and University of Birmingham requires follow up data on cancer incidence and mortality rate for use in the UK Study of Families of Ataxia Telangiectasia (A-T) Patients in order to estimate the cancer risks to individuals carrying a mutation in the ATM gene. The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted that the application had not previously been presented at an IGARD business as usual (BAU) meeting. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD queried the statement in supporting document 4.2, the Health Research Authority Confidentiality Advisory Group (HRA CAG) dated the 3rd February 2021, that stated *"Anonymisation is also impractical as the data on cancer incidence and mortality need to be linked to the questionnaire data in order to conduct the analysis"*; and noted that if NHS Digital were holding the cohort identities, it was not clear why the applicant needed to retain direct identifiers, because they could link the data from NHS Digital via a pseudonym. IGARD asked

	that section 1 (Abstract) and section 5(a) (Objective for Processing) were updated with further clarity as to whether it was possible for the study to continue with a pseudonymised dataset. IGARD noted the statement in section 5(a) to the GP providing **consent** to contact, and asked that this statement was checked with the applicant, and updated to state that *"the GP **facilitated** contact, as was common practice at the time"*, if this reflected the factual scenario. IGARD queried the statement in section 5(a) *"Participants completed questionnaires, providing details on their parents, siblings and children, and the details of more **distant relatives** who were known to have had cancer."*; and asked that clarity was provided in section 5(a) of who the data subjects are, noting the reference to *"distant relatives".* In addition, IGARD asked that confirmation was provided in section 5(a), of the level of data that was held for the members of the cohort, and when referring to *"distant relatives"*, and how far this extended. IGARD noted the inconsistent refences to cohort numbers, and asked that in line with NHS Digital's DARS Standard for Data minimisation, section 3 (Datasets Held / Requested) and section 5(b) (Processing Activities) were updated with an indicative cohort size. IGARD noted the reference in the data minimisation column in section 3(b) (Additional Data Access Requested) to *"limited to the cohort size"* with a cohort number stated; IGARD asked that this was amended to include the correct indicative cohort size which aligned with the details give in the rest of the application". IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD noted the excellent yielded benefits in section 5(d) (iii) (Yielded Benefits); however queried the reference to *"obligate carriers"* when referring to the NHS Breast Screening Programme, and asked this was updated with a further explanation, in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the references in section 5 (Purpose / Methods / Outputs) to *"the CCG"*, and asked that this was updated and replaced with *"commissioning bodies"* in light of the imminent CCG structure changes. IGARD noted that as section 5 forms NHS Digital's data uses register, the reference in section 5 to *"lifestyle risk factors"* was updated to another form of wording, for example, social or economic determinants of health. In the absence of any published transparency materials, and given the rare genetic component that was being captured via the original cohort, IGARD suggested that the applicant keep the Ataxia Telangiectasia (AT) Society members up to date with recent developments and the continued flow of NHS Digital data. IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4 (Privacy Notice), in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the data subjects: a) To provide clarity in section 5(a) who the data subjects are, for example, noting the reference to *"distant relatives"* within the application.

	b) To provide confirmation in section 5(a) what level of data is held for the members of the cohort, and when referring to *"distant relatives"*, how far does this extend. 2. In respect of the cohort size: a) To update section 3 and section 5(a) with an indicative size of the cohort. b) To update section 3(b) to include the correct indicative cohort size which aligns with the details provided in the rest of the application. 3. To update section 1 and section 5(a) to clarify if it is possible for the study to continue with a pseudonymised dataset. 4. To update the statement in section 5(a) in respect of the GP providing **consent** to contact, to state that *"the GP **facilitated** contact, as was common practice at the time"*, (if this reflects the factual scenario). 5. To replace the references in section 5 from *"the CCG"* to *"commissioning bodies"*. 6. To update section 5 to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 7. As section 5 forms NHS Digital's public data release register, to update reference in section 5 to *"lifestyle risk factors"* to another form of wording, for example, social or economic determinants of health. 8. To update the excellent yielded benefit in section 5(d) (iii) to provide a further explanation on the reference to *"obligate carriers"*. The following advice was given: 1. In the absence of any published transparency materials, and given the rare genetic component that is being captured via the original cohort, IGARD suggested that the applicant keep the AT Society members up to date with recent developments and the continued flow of NHS Digital data. 2. IGARD advised that NHS Digital draw the applicant's attention to the contractual obligation in section 4, in respect of maintaining a UK GDPR compliant, publicly accessible transparency notice throughout the life of this agreement.
4 **4.1**	<u>Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent</u> Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). <u>NIC-20951-D2K6S-v7 Office for National Statistics (ONS)</u> The purpose of this application was for the data to be processed in conjunction with other administrative data for estimating internal and international migration, the local authority distribution of international migrants component of change for the mid-year estimates and small area population estimates within England and Wales and estimating migration between England and Wales, Scotland and Northern Ireland. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 22nd July 2021, where IGARD were unable to make a recommendation as not all the necessary information was available in order for IGARD to make a full assessment. IGARD noted that on the 1st December 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise an extension. In addition, the SIRO and a senior colleague from DARS attended the meeting to provide IGARD with a verbal update.

	NHS Digital advised that the current Data Sharing Agreement was due to expire the week commencing the 13th December 2021, and work was ongoing to address a number of issues, including the points raised by IGARD previously. NHS Digital confirmed that SIRO had approved an extension and renewal until the end of February 2022; and that only datasets previously flowed would be permitted to flow, to allow ONS to undertake their statutory functions and to share agreed datasets with Scotland and Northern Ireland. NHS Digital advised that the new variables requested in July 2021, would not flow as part of the updated DSA. NHS Digital confirmed that the next iteration of the application would be presented at a future IGARD BAU meeting. IGARD noted and thanked NHS Digital for the written and verbal update and confirmed that they supported NHS Digital's assessment that the next iteration should be brought to a future IGARD BAU meeting. IGARD advised that given the complexity of the application and the outstanding actions, they would be supportive of the applicant attending an IGARD BAU meeting prior to the application being submitted for review, for further discussions to support the progression of the application.
4.2	<u>NIC-10328-S0H5J-v10 Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust</u> The purpose of this application was for access to NHS Digital's On-line Portal system, which enables organisations to access Hospital Episode Statistics (HES) data for a wide range of data analytical purposes. The system is an online analytical processing tool through which the users of this organisation data has access to a wide range of analytical, graphical, statistical and reporting functions. The North East Quality Observatory Service (NEQOS) uses the system to support the measurement of quality of care, including care delivered in hospital. NEQOS provides quality measurement for NHS organisations (both providers and commissioners) and leads on the measurement programmes for the Academic Health Science Network in North East and North Cumbria. IGARD noted that this application was last reviewed by the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 29th July 2016. IGARD noted that on the 23rd November 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a fixed term renewal for six months, with a special condition requiring the applicant to provide additional information about some commercial aspects of their work. In addition, NHS Digital have confirmed that the next iteration of the application would be presented at a future IGARD BAU meeting. IGARD noted and thanked NHS Digital for the written update and confirmed that they supported NHS Digital's assessment that the next iteration should be brought to a future IGARD BAU meeting.
5	<u>Oversight & Assurance</u> IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital. Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any Data Access Request Service (DARS) applications as part of their oversight and assurance role.

	IGARD noted that they had requested, an IG COVID-19 release register suite of documents on a particular data release for review by IGARD as part of their oversight and assurance, and as agreed in June 2020 with the Executive Director Privacy, Transparency and Ethics (PTE) when it had been agreed that IGARD review an agreed number per month, by way of a review of all documentation revised by PTE, and as part of continuous improvement and quality. IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was July 2021.
6	<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. IGARD noted that at the request of NHS Digital, the COVID-19 response meeting on Tuesday, 7th December 2021 was cancelled.
7 **7.1** **7.2**	<u>AOB:</u> <u>Head of Data Access Update</u> The Head of Data Access attended (part of) the meeting as part of her regular catch-up with IGARD. <u>'Sex' versus 'Gender'</u> IGARD noted that in August 2021 IGARD ask NHS Digital to respond to a query of how DARS and Data Production deal with 'sex' (a person's physical characteristics at birth) versus 'gender' (the socially constructed roles, behaviours, expressions and identities) as data fields and a means of linking and extracting data. IGARD noted that a briefing paper had been provided, that addressed some of the concerns raised. IGARD welcomed and thanked NHS Digital for providing the briefing paper, and advised that a further discussion would take place at a future IGARD BAU meeting, with both the author of the paper and a member of the DARS Senior Approval Team. 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 03/12/21

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-359651-H3R1P-v5.4	University of Oxford	04/11/2021	1. In respect of the data controllership and in line with NHS Digital's DARS Standard for Data Controllers: a) To clarify which legal entities should be considered a Data Controller, as borne out of the facts, with particular reference to NHS Improvement (Monitor and NHS TDA). b) To update the application as necessary.	IGARD Chair	IGARD Chair	None
NIC-144568-D7G6V-v3.	Guy's and St Thomas' NHS Foundation Trust	23/09/2021	1. In respect of the stated research aims: a) To adjust the research goals and outputs in section 5, to reflect the limited data requested in section 3(b); or, b) To request, the relevant additional datasets which would reveal vaccine status, and more accurately inform infection status, and include in section 3(b).	IGARD members	Quorum of IGARD members	**IGARD Comments / Request:** *"With regard to the statement under amendment 1, noting that DARS have already informed us that they have received advice from PTE regarding datasets that concern those who have died but reveal who is living within the dissemination of data:*

						*"continue to apply the clause that GDPR does not apply to data solely relating to deceased individuals until such time as the guidance changes". It would seem prudent that the data is offered the same protection under UK GDPR (and a legal basis is established) until such time that the assessment has been made that UK GDPR clearly does not apply, the statement here suggests that IGARD does not agree that the UK GDPR does not apply to deceased individuals – **that is not the issue** and should be reworded"*
NIC-402414-Q5R7Y-v0.4	Public Health Scotland	28/10/2021	1. In respect of Data Minimisation and in line with the NHS Digital DARS Standard for Data Minimisation: a) To provide a rationale in section 3 of the large volume of data requested, and b) To provide a clearer justification in section 5 as to why all English data has been requested, for example why the applicant cannot look at similar geographies, type of Hospital Trust etc (as raised by IGARD on 18th May 2017), and c) To provide evidence as to how the applicant has used the data historically,	IGARD members	Quorum of IGARD members	**IGARD Comments / Request:** *"IGARD members noted amendment 2a did not appear to have been actioned and NWIS and BAD's had not been spelt out in full. Noting section 5 forms NHS Digital's data uses register, IGARD reminded DARS that all acronyms*

			which has not been included in the dashboard, and if not used, provide a justification as to why this data cannot be destroyed. 2. In respect of the Yielded Benefits in section 5(d)(iii) a) To update the yielded benefits in line with the NHS Digital DARS Standard for Expected Measurable Benefits, and b) Given the significant volume of data, to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally.			*should be spelt out on first use."*
NIC-362267-P1W2X-v1.2	NHS Bradford District and Craven CCG	11/11/2021	1. In respect of the security arrangements a) To provide written confirmation (such as an e-mail) that the DSPT action plan has been finalised and that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place. b) To upload the written confirmation from NHS Digital's Security Advisor to NHS Digital's CRM system for future reference.	IGARD Chair	IGARD Chair	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:

- None

Optum Health Solutions UK Limited Class Actions:

- None

Graphnet Class Actions:

- None