Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 4 November 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine (Chair)	IGARD Chair
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Louise Dunn	Data Access Request Service (DARS) (Observer: items 1 - 7)
Karen Myers	IGARD Secretariat
Denise Pine	Data Access Request Service (DARS)
Joanna Warwick	Data Access Request Service (DARS) (Item 5)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:** Maria Clark noted professional links to the Royal College of Obstetricians and Gynaecologist (NIC-359651-H3R1P), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 28th October 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**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	University of Oxford: MR1055 - HPS2-THRIVE Treatment of HDL to Reduce the Incidence of Vascular Events (Presenter: Denise Pine) NIC-147885-0TV66-v9.3 **Application:** This was an extension and renewal to permit the holding and processing of identifiable Medical Research Information Service (MRIS) Cause of Death Report, MRIS Cohort Event Notification Report and MRIS Flagging Current Status Report. It was also an amendment to **1)** continue extended follow up of the HPS2-THRIVE UK cohort in the HPS2-THRIVE Trial Legacy Study; **2)** to change the common law duty of confidence to section 251 support; **3)** to request additional identifiable datasets including HES Admitted Patient Care (HES APC), Mental Health Minimum Data Set (MHMDS), Mental Health and Learning Disabilities Data Set (MHLDS), Mental Health Services Data Set (MHSDS), Bridge file: HES to MHMDS, Cancer Registration Data, Civil Registration (Deaths) and Demographics data. The HPS2-THRIVE (Treatment of HDL to Reduce the Incidence of Vascular Events) study was a randomised, international multi-centre trial of 2g of extended-release niacin (a B vitamin that is made and used by the body to turn food into energy) and 40 mg of laropiprant (a drug used in combination with niacin to reduce blood cholesterol) or a matching placebo daily in 25,673 participants (8,035 in the UK, 10,932 in China and 6,706 in Scandinavia (Denmark, Norway, Finland & Sweden)) with a history of vascular disease that ran in 245 sites in six countries (including 89 UK clinical centres). The initial trial results were published in 2014. The study showed that participants allocated to niacin/laropiprant did not have a lower risk of major vascular events than those allocated to placebo, but the niacin/laropiprant did increase the risk of serious adverse events, particularly diabetes diagnosis and control, bleeding and infection. The purpose of this application is to determine factors that contribute to the health of trial participants in the longer-term. The research objectives are: **1)** to determine whether participants randomly allocated to treatments leading to lower levels of low-density lipoprotein (LDL) cholesterol have a lower risk of dementia; **2)** to determine whether participants randomly allocated to treatments leading to lower levels of LDL cholesterol have other long-term health effects; **3)** to measure the association between baseline and in-trial vascular risk measures with future dementia; and **4)** to determine the association between deoxyribonucleic acid (DNA) and plasma markers with dementia and other long-term health effects. The cohort will consist of participants of the original randomised controlled trial, originally recruited in 2007, however some participants have been lost to follow-up, withdrawn from the study or are now deceased; therefore the current number of participants is now 7,456. The study is relying on s251 of the NHS Act 2006, for the flow of data in and out of NHS Digital. NHS Digital advised IGARD that they hold the details of the existing HPS2-THRIVE UK cohort, and that there would be no new flows of identifiable data to NHS Digital, and that as part of this Data Sharing Agreement (DSA), identifiers would be removed by NHS Digital before the data was sent back to the University of Oxford, therefore making the datasets pseudonymised.

	Discussion: IGARD noted that the application had not previously been presented at an IGARD business as usual (BAU) meeting. IGARD noted the similarities between this application, and items 3.2 (NIC-148341-TC6TD) and 3.3 (NIC-148069-ZB4GM), and queried if there were any current or planned pooling of data, or combination of processing between the three applications; noting that this was not addressed in the application, IGARD asked that section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) were updated with a description if relevant. 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 noted the verbal update from NHS Digital in respect of the data flowing from NHS Digital to the University of Oxford being pseudonymised and not identifiable, however queried the information in section 3 (Datasets Held / Requested), that stated throughout that the data requested was *"identifiable"*. NHS Digital advised that although the identifiers would be removed before the data flowed to the University of Oxford, there was the possibility that the data subjects could be reidentified via a study number, and therefore the data was being treated as identifiable. IGARD noted the verbal update from NHS Digital, and asked that for transparency, a brief explanation was provided in section 5 (Purpose / Methods / Outputs), as to why the data was treated as *"identifiable".* In addition, IGARD noted in section 5 that the University of Oxford would continue to hold the original identifiers, and noting that the reason for this was not clear, asked that section 5 was updated with confirmation. IGARD also noted supporting document 2.2, the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support dated the 6th December 2019, where it stated *"The applicant would only hold and analyse datasets with trial numbers, the identifiers and linkage key held separately. The linkage key would be held by NHS Digital."*; and asked that confirmation was provided as to how the University of Oxford would transition away from holding identifiers, noting NHS Digital would continue to hold the linkage key. IGARD noted that the study was part of a large global study and queried if the data under this DSA would be shared with any of the international parties referenced in section 5(a). NHS Digital advised that they had queried this with the applicant, who had confirmed that there would be **no** data sharing with any international parties outside the stated territory of use, England and Wales. IGARD noted the verbal update from NHS Digital, and asked that for transparency, written confirmation was provided in section 5(a), that there would be **no** data sharing with the international parties referenced in the application. IGARD had a lengthy discussion in relation to NHS Digital data that had already flowed for cohort members using consent as the legal basis, given that consent was no longer judged adequate and had been supplanted by s251. IGARD queried if the University of Oxford had the relevant support to continue to hold the data previously disseminated for those individuals with National Data Opt-outs (NDOs), given that the NDO is typically applied where s251 is the legal basis. IGARD therefore asked that the applicant queried this with HRA CAG; and that once a response had been received, asked that section 1 (Abstract) and section 5(a) were updated for transparency. IGARD also asked that a copy of the response from HRA CAG was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted the statement in section 5(b) that participants who *"…have decided that they do not wish their data to be used in this study will be able to opt out."*, and noting that the

	reference to 'opting out' could be confused with the NDO, asked that for clarity, this reference was amended to refer to participants *"withdrawing consent to participate in the study"*. IGARD queried the statement in section 5(a) *"Participants who consented to have their medical records followed up also consented to providing blood samples for the genomic arm of this study… This will involve sending pure DNA samples"*. IGARD expressed concern that the blood samples provided by participants in 2007 – 2010, appeared to be being processed without further specific consent; or if consent had been taken for the assays, whether the consent taken at the time covered the dramatically different technology available in the present day. IGARD queried if this specific point had been discussed with the Research Ethics Committee (REC). IGARD acknowledged that whilst no formal guidance in respect of this has been issued by relevant bodies, they, and many other commentators, were of the view that genetic data may be considered 'personal data' under UK GDPR (**not** anonymous), see for example the ICO commissioned analysis by the PHG Foundation. In addition, IGARD queried if the outputs from the DNA analysis carried out on the blood samples previously provided by participants, would be linked with the NHS Digital data; and asked that this was clarified in section 5(a). IGARD noted that the applicant was not in contact with the cohort and that some patient and public involvement and engagement (PPIE) work had been undertaken with members of the public on similar studies. IGARD suggested that given the long running nature of the study and projected work onto 2035, the applicant should consider setting up or utilising a PPIE group to discuss future plans, including, but not limited to, further genetic research on blood samples provided by participants. IGARD recommended reference to the helpful HRA guidance on Public Involvement. IGARD noted the global impact of the study, however advised that the application was predominantly silent on the benefits of the study to date, as summarised on the study website. IGARD asked that section 5(a) and section 5(d) (Benefits) were updated with a brief lay summary / bullets outlining the benefits of the study, for example, the lives that had been saved as a result of clinicians stopping prescribing the drugs that were the subject of the study; and in line with NHS Digital's DARS Standard for Objective for Processing and NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted that Section 5(d) (iii) (Yielded Benefits) did not appear to be in line with the NHS Digital DARS Standard for Expected Measurable Benefits and asked that this section was updated. In addition, asked that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii) and to ensure these are clear about the benefits to both patients and the health care system more generally. IGARD queried the yielded benefit in section 5(d) (iii) relating to ischaemic strokes, and asked that this was updated with further clarification on this point, so that the benefit was understandable to a lay reader; and in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that section 5(e) (Is the Purpose of this Application in Anyway Commercial) stated there was no commercial funding, however queried if this was correct, for example, was the 'original' study funded by a commercial organisation, or was there any ongoing commercial funding; and asked that for transparency, section 5(e) was updated to reflect past or present commercial funding, and, in line with NHS Digital DARS Standard for Commercial Purpose. IGARD noted a number of acronyms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, 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 *"HRA CAG"*. IGARD queried the statement in section 5(a) *"Further data releases will allow the study team to continue follow up into the extremely long term."*, and asked that this was updated to a more precise description, for example *"entire lifespan including cause of death".* IGARD queried the statement in section 1 *"…the special condition does not include instruction to destroy the data in light of current guidance pending the Covid-19 enquiry [sic]".* NHS Digital advised IGARD that as per the current (NHS Digital) advice, there was currently a pause on the destruction of NHS Digital data, in light of the forthcoming public COVID-19 inquiry. IGARD noted the verbal update from NHS Digital, however suggested that the blanket cessation of destruction of data may not be the best course of action in all cases, for example, noting that this study was not connected or in any way related to COVID-19 and that the UK General Data Protection Regulation (UK GDPR) principles still applied. IGARD advised that they would wish to review this application when it comes up for amendment, to ensure continued alignment with the HRA CAG specific conditions of support. **Outcome:** recommendation to approve subject to the following condition: 1. To provide written confirmation in section 5(a) that there will be **no** data sharing with the international parties referenced in the application. The following amendments were requested: 1. To provide a description in section 5(a) and section 5(b), of any current or planned pooling of data or combination of processing with NIC-148341-TC6TD and NIC-148069-ZB4GM. 2. To provide a brief explanation in section 5 as to why the data is treated as *"identifiable"*, as per the verbal update from NHS Digital. 3. In respect of the identifiers: a) To provide confirmation in section 5 as to why the University of Oxford are continuing to hold identifiers. b) In line with the HRA CAG support, to provide confirmation how the University of Oxford will transition away from holding identifiers, (noting NHS Digital will continue to hold the linkage key). 4. In respect of the NDO: a) The applicant to confirm with HRA CAG: where NHS Digital data has already flowed for cohort members who have subsequently exercised the NDO, do they have support to continue to hold the previously disseminated data for those individuals? b) To update section 1 and section 5(a) to reflect the response from HRA CAG for transparency. c) NHS Digital to upload a copy of the HRA CAG confirmation on to their CRM system for future reference. 5. For the avoidance of any confusion with the NDO, to amend the reference in section 5(b) that participants *"…will be able to opt out"*, to refer instead to participants *"withdrawing consent to participate in the study"*. 6. To state in section 5(a) whether or not the outputs from the DNA analysis carried out on blood samples provided by participants previously, will be linked with NHS Digital data. 7. Noting the global impact of the study, to update section 5(a) and section 5(d) with a brief lay summary / bullets outlining the benefits of the study, for example, the lives that

	have been saved as a result of clinicians stopping prescribing the drugs that were the subject of the study. This summary could be directly copied over from the study website. 8. To update section 5(e) to reflect any commercial funding past or present, in line with NHS Digital DARS Standard for Commercial Purpose 9. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout to ensure acronyms be defined upon first use, for example *"HRA CAG"*. 10. To update the reference in section 5(a) from *"…extremely long term"* to a more precise description, for example *"entire lifespan including cause of death".* 11. 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 global high impact, to provide 2 or 3 specific yielded benefits accrued to date. c. To provide further clarification of the yielded benefit~~s~~, relating to ischaemic strokes so that the benefit is understandable to a lay reader. The following advice was given: 1. IGARD noted that the applicant was not in contact with the cohort and some PPIE work had been undertaken with members of the public on similar studies. IGARD suggested that given the long running nature of the study and projected work onto 2035, the applicant should consider setting up or utilising a PPIE group to discuss future plans, including (but not limited to) further genetic research on blood samples provided by participants. IGARD recommended reference to the helpful HRA guidance on Public Involvement. 2. IGARD noted the narrative in the abstract and the verbal update from NHS Digital in respect of the current guidance from NHS Digital in respect of pausing the destruction of data, in light of the forthcoming public COVID-19 inquiry. IGARD suggested that the blanket cessation of destruction of data may not be the best course of action in all cases, for example, noting that this study was not connected in any way related to COVID-19 and that UK GDPR principles still applied. 3. IGARD advised that they would wish to review this application when it comes up for amendment, to ensure continued alignment with the HRA CAG specific conditions of support. **Risk Area:** IGARD expressed concern that the blood samples provided by participants in 2007 – 2010, appeared to be being processed without further specific consent (or if consent had been taken for the assays, whether the consent taken at the time covered the dramatically different technology available in the present day). IGARD queried if this specific point had been discussed with the REC. IGARD acknowledged that whilst no formal guidance in respect of this has been issued by relevant bodies, they, and many other commentators, were of the view that genetic data may be considered 'personal data' under UK GDPR (**not** anonymous), see for example the ICO commissioned analysis by the PHG Foundation. It was agreed the conditions would be approved out of committee (OOC) by the IGARD Chair.
3.2	University of Oxford: MR706 - SEARCH: Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (Presenter: Denise Pine) NIC-148341-TC6TD-v8.3 **Application:** This was an amendment to **1)** continue extended follow up of the SEARCH study cohort in the SEARCH trial legacy study; **2)** to change the common law duty of confidence to section 251 support; **3)** to request additional identifiable datasets including HES Admitted

	Patient Care (HES APC), Mental Health Minimum Data Set (MHMDS), Mental Health and Learning Disabilities Data Set (MHLDS), Mental Health Services Data Set (MHSDS), Bridge file: HES to MHMDS, Cancer Registration Data, Civil Registration (Deaths) and Demographics data. SEARCH was a randomised, multi-centre, factorial trial of low-density lipoprotein (LDL) cholesterol lowering, comparing higher versus standard dose simvastatin (a drug used to lower cholesterol for people diagnosed with high blood cholesterol), and homocysteine (an amino acid) lowering comparing folic acid and vitamin B12 supplementation versus placebo in 12,064 patients with an average age of 64 and with a history of heart attacks (myocardial infarction (MI)). It was run in 88 UK clinical centres for ten years. Participants in SEARCH were recruited to the trial between September 1998 and October 2001, with all final follow-up assessments completed by June 2008. The initial trial results of the ten-year follow-up were published in 2010. This study, in combination with other available data, showed that additional LDL cholesterol lowering with a high dose statin further reduced major vascular events, but that folic acid and vitamin B12 supplementation did not have beneficial effects on vascular outcomes. The purpose of this application is to determine factors that contribute to the health of trial participants in the longer-term. The research objectives are: **1)** to determine whether participants randomly allocated to treatments leading to lower levels of LDL cholesterol or lower homocysteine levels have a lower risk of dementia; **2)** to determine whether participants randomly allocated to treatments leading to lower levels of LDL cholesterol or lower homocysteine levels have other long-term health effects; **3)** to measure the association between baseline and in-trial vascular risk measures with future dementia; and **4)** to determine the association between deoxyribonucleic acid (DNA) and plasma markers with dementia and other long-term health effects. The cohort will consist of participants of the original randomised controlled trial, originally recruited / consented, however some participants have been lost to follow-up, withdrawn from the study or are now deceased; therefore the current number of participants is now 10,389. The study is relying on s251 of the NHS Act 2006, for the flow of data in and out of NHS Digital. NHS Digital advised IGARD that they hold the details of the existing SEARCH study cohort, and that there would be no new flows of identifiable data to NHS Digital, and that as part of this Data Sharing Agreement (DSA), identifiers would be removed before the data was sent back to the University of Oxford, therefore making the datasets pseudonymised. NHS Digital advised IGARD that section 1 (Abstract) of the application stated that the application was a *"renewal"*, however confirmed that this was incorrect and would be amended to correctly reflect that it was an *"amendment"*. **Discussion:** IGARD noted that the application had not previously been presented at an IGARD business as usual (BAU) meeting. IGARD noted the verbal update from NHS Digital, in respect of the application being submitted for an amendment and not a renewal, and supported the update to the application to reflect this. IGARD noted the similarities between this application, and items 3.1 (NIC-147885-0TV66) and 3.3 (NIC-148069-ZB4GM), and queried if there were any current or planned pooling of data, or combination of processing between the three applications; and noting that this was not

	addressed in the application, asked that section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) were updated with a description if relevant. 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 noted the verbal update from NHS Digital in respect of the data flowing from NHS Digital to the University of Oxford being pseudonymised and not identifiable, however queried the information in section 3 (Datasets Held / Requested), that stated throughout that the data requested was *"identifiable"*. NHS Digital advised that although the identifiers would be removed before the data flowed to the University of Oxford, there was the possibility that the data subjects could be reidentified via a study number, and therefore the data was being treated as identifiable. IGARD noted the verbal update from NHS Digital, and asked that for transparency, a brief explanation was provided in section 5 (Purpose / Methods / Outputs), as to why the data was treated as *"identifiable".* In addition, IGARD noted in section 5 that the University of Oxford would continue to hold the original identifiers, and noting that the reason for this was not clear, asked that section 5 was updated with confirmation. IGARD also noted supporting document 2.1, the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support dated the 6th December 2019, where it stated *"The applicant would only hold and analyse datasets with trial numbers, the identifiers and linkage key held separately. The linkage key would be held by NHS Digital."*; and asked that confirmation was provided as to how the University of Oxford would transition away from holding identifiers, noting NHS Digital would continue to hold the linkage key. IGARD had a lengthy discussion in relation to NHS Digital data that had already flowed for cohort members using consent as the legal basis, given that consent was no longer judged adequate and had been supplanted by s251. IGARD queried if the University of Oxford had the relevant support to continue to hold the data previously disseminated for those individuals with National Data Opt-outs (NDOs), given that the NDO is typically applied where s251 is the legal basis. IGARD therefore asked that the applicant queried this with HRA CAG; and that once a response had been received, asked that section 1 (Abstract) and section 5(a) were updated for transparency. IGARD also asked that a copy of the response from HRA CAG was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted the statement in section 5(b) that participants who *"…have decided that they do not wish their data to be used in this study will be able to opt out."*, and noting that the reference to 'opting out' could be confused with the NDO, asked that for clarity, this reference was amended to refer to participants *"withdrawing consent to participate in the study"*. IGARD queried the statement in section 5(a) *"Participants who consented to have their medical records followed up also consented to providing blood samples for the genomic arm of this study… This will involve sending pure DNA samples"*. IGARD expressed concern that the blood samples provided by participants in 2007 – 2010, appeared to be being processed without further specific consent; or if consent had been taken for the assays, whether the consent taken at the time covered the dramatically different technology available in the present day. IGARD queried if this specific point had been discussed with the Research Ethics Committee (REC). IGARD acknowledged that whilst no formal guidance in respect of this has been issued by relevant bodies, they, and many other commentators, were of the view that

	genetic data may be considered 'personal data' under UK GDPR (**not** anonymous), see for example the ICO commissioned analysis by the PHG Foundation. In addition, IGARD queried if the outputs from the DNA analysis carried out on the blood samples previously provided by participants, would be linked with the NHS Digital data; and asked that this was clarified in section 5(a). IGARD noted that the applicant was not in contact with the cohort and that some patient and public involvement and engagement (PPIE) work had been undertaken with members of the public on similar studies. IGARD suggested that given the long running nature of the study and projected work into 2035, the applicant should consider setting up or utilising a PPIE group to discuss future plans, including, but not limited to, further genetic research on blood samples provided by participants. IGARD recommended reference to the helpful HRA guidance on Public Involvement. IGARD noted the global impact of the study, however advised that the application was predominantly silent on the benefits of the study to date, as summarised on the study website. IGARD asked that section 5(a) and section 5(d) (Benefits) were updated with a brief lay summary / bullets outlining the benefits of the study, and in line with NHS Digital's DARS Standard for Objective for Processing and NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted that Section 5(d) (iii) (Yielded Benefits) did not appear to be in line with the NHS Digital DARS Standard for Expected Measurable Benefits and asked that this section was updated. In addition, asked that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii) and to ensure these are clear about the benefits to both patients and the health care system more generally. IGARD queried the yielded benefit in section 5(d) (iii) relating to ischaemic strokes, and asked that this was updated with further clarification on this point, so that the benefit was understandable to a lay reader; and in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted a number of acronyms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, 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 *"HRA CAG"*. IGARD queried the statement in section 5(a) *"Further data releases will allow the study team to continue follow up into the extremely long term."*, and asked that this was updated to a more precise description, for example *"entire lifespan including cause of death".* IGARD queried the statement in section 1 *"…the special condition does not include instruction to destroy the data in light of current guidance pending the Covid-19 enquiry [sic]."*. NHS Digital advised IGARD that as per the current (NHS Digital) advice, there was currently a pause on the destruction of NHS Digital data, in light of the forthcoming public COVID-19 inquiry. IGARD noted the verbal update from NHS Digital, however suggested that the blanket cessation of destruction of data may not be the best course of action in all cases, for example, noting that this study was not connected in any way related to COVID-19 and that the UK General Data Protection Regulation (UK GDPR) principles still applied. IGARD advised that they would wish to review this application when it comes up for amendment, to ensure continued alignment with the HRA CAG specific conditions of support. **Outcome:** recommendation to approve

	The following amendments were requested: 1. To provide a description in section 5(a) and section 5(b), of any current or planned pooling of data or combination of processing with NIC-147885-0TV66 and NIC-148069-ZB4GM. 2. To provide a brief explanation in section 5 as to why the data is treated as *"identifiable"*, as per the verbal update from NHS Digital. 3. In respect of the identifiers: a) To provide confirmation in section 5 as to why the University of Oxford are continuing to hold identifiers. b) In line with the HRA CAG support, to provide confirmation how the University of Oxford will transition away from holding identifiers, (noting NHS Digital will continue to hold the linkage key). 4. In respect of the NDO: a) The applicant to confirm with HRA CAG: where NHS Digital data has already flowed for cohort members who have subsequently exercised the NDO, do they have support to continue to hold the previously disseminated data for those individuals? b) To update section 1 and section 5(a) to reflect the response from HRA CAG for transparency. c) NHS Digital to upload a copy of the HRA CAG confirmation on to their CRM system for future reference. 5. For the avoidance of any confusion with the NDO, to amend the reference in section 5(b) that participants *"…will be able to opt out"*, to refer instead to participants "*withdrawing consent to participate in the study*". 6. To state in section 5(a) whether or not the outputs from DNA analysis carried out on blood samples provided by participants previously, will be linked with NHS Digital data. 7. Noting the global impact of the study, to update section 5(a) and section 5(d) with a brief lay summary / bullets outlining the benefits of the study. This summary could be directly copied over from the study website. 8. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout, to ensure acronyms be defined upon first use, for example *"HRA CAG"*. 9. To update the reference in section 5(a) from *"…extremely long term"* to a more precise description, for example *"entire lifespan including cause of death".* 10. 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 global high impact, to provide 2 or 3 specific yielded benefits accrued to date. c. To provide further clarification of the yielded benefits, relating to ischaemic strokes so that the benefit is understandable to a lay reader. The following advice was given: 1. IGARD noted that the applicant was not in contact with the cohort and some PPIE work had been undertaken with members of the public on similar studies. IGARD suggested, that given the long running nature of the study and projected work into 2035, the applicant should consider setting up or utilising a PPIE group to discuss future plans, including (but not limited to) further genetic research on blood samples provided by participants. IGARD recommended reference to the helpful HRA guidance on Public Involvement.

	2. IGARD noted the narrative in the abstract and the verbal update from NHS Digital in respect of the current guidance from NHS Digital in respect of pausing the destruction of data, in light of the forthcoming public COVID-19 inquiry. IGARD suggested that the blanket cessation of destruction of data may not be the best course of action in all cases, for example, noting that this study was not connected in any way related to COVID-19 and the UK GDPR principles still applied. 3. IGARD advised that they would wish to review this application when it comes up for amendment, to ensure continued alignment with the HRA CAG specific conditions of support. **Risk Area:** IGARD expressed concern that the blood samples provided by participants in 2007 – 2010, appeared to be being processed without further specific consent (or if consent had been taken for the assays, whether the consent taken at the time covered the dramatically different technology available in the present day). IGARD queried if this specific point had been discussed with the REC. IGARD acknowledged that whilst no formal guidance in respect of this has been issued by relevant bodies, they, and many other commentators, were of the view that genetic data may be considered 'personal data' under UK GDPR (**not** anonymous), see for example the ICO commissioned analysis by the PHG Foundation.
3.3	University of Oxford: MR542 - MRC/BHF HEART PROTECTION STUDY (Presenter: Denise Pine) NIC-148069-ZB4GM-v9.4 **Application:** This was an extension and renewal to permit the holding and processing of identifiable Hospital Episode Statistics Admitted Patient Care (HES APC), Medical Research Information Service (MRIS) Cause of Death Report, MRIS Cohort Event Notification Report, MRIS Flagging Current Status Report and MRIS Members and Postings Report. It was also an amendment to **1)** request permission to use the data provided for the Medical Research Council/British Heart Foundation (MRC/BHF) Heart Protection Study (HPS) cohort for long term follow up; **2)** to change the common law duty of confidence to section 251 support; **3)** to request additional identifiable datasets including HES Admitted Patient Care (HES APC), Mental Health Minimum Data Set (MHMDS), Mental Health and Learning Disabilities Data Set (MHLDS), Mental Health Services Data Set (MHSDS), Bridge file: HES to MHMDS, Cancer Registration Data, Civil Registration (Deaths) and Demographics data. The Heart Protection Study (HPS) was a large randomised controlled trial. Between 1994 and 1997, 20,536 individuals in the UK at increased risk of coronary heart disease were randomised to 40mg simvastatin daily versus matching placebo, and (in a 2X2 factorial design) to anti-oxidant vitamin supplementation with vitamins E, C and beta-carotene versus placebo. Participants took trial medications for an average of 5-years (scheduled treatment period), and the main trial closed in 2001. The aim was to study the overall effects on survival by preventing heart attacks, strokes and other major vascular events. The purpose of this application is to determine factors that contribute to the health of trial participants in the longer term. The principal research objectives are to directly assess the very long-term effects of both: a)) Around 5-years of statin treatment (40mg) versus matching placebo, and b) Around 5-years use of antioxidant vitamin supplements (vitamin E, vitamin C, and beta-carotene) versus matching placebo, on major health events (i.e. major vascular events, cancer, dementia) and death. Secondary research objectives are to investigate associations between both various patient characteristics (e.g. age, gender, prior disease, blood pressure, height and weight) and also blood test results (including genetic analyses),

	and the risk of developing important medical conditions (e.g. heart attacks, strokes, cancers, and dementia) in later life. The cohort will consist of participants of the original randomised controlled trial, originally recruited / consented, however some participants have been lost to follow-up, withdrawn from the study or are now deceased; therefore, the current number of participants is now 18,715. The study is relying on s251 of the NHS Act 2006, for the flow of data in and out of NHS Digital. The application was previously considered on the 18th October 2018 where IGARD were unable to make a recommendation. NHS Digital advised IGARD that they hold the details of the existing MRC/BHF HPS cohort, and that there would be no new flows of identifiable data to NHS Digital, and that as part of this Data Sharing Agreement (DSA), identifiers would be removed before the data was sent back to the University of Oxford, therefore making the datasets pseudonymised. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 18th October 2018. IGARD noted the similarities between this application, and items 3.1 (NIC-147885-0TV66) and 3.2 (NIC-148341-TC6TD), and queried if there were any current or planned pooling of data, or combination of processing between the three applications; and noting that this was not addressed in the application, asked that section 5(a) (Objective for Processing) and section 5(b) (Processing Activities) were updated with a description if relevant. 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 noted the verbal update from NHS Digital in respect of the data flowing from NHS Digital to the University of Oxford being pseudonymised and not identifiable, however queried the information in section 3 (Datasets Held / Requested), that stated throughout that the data requested was *"identifiable"*. NHS Digital advised that although the identifiers would be removed before the data flowed to the University of Oxford, there was the possibility that the data subjects could be reidentified via study numbers, and therefore the data was being treated as identifiable. IGARD noted the verbal update from NHS Digital, and asked that for transparency, a brief explanation was provided in section 5 (Purpose / Methods / Outputs), as to why the data was treated as *"identifiable".* In addition, IGARD noted in section 5 that the University of Oxford would continue to hold the original identifiers, and noting that the reason for this was not clear, asked that section 5 was updated with confirmation. IGARD also noted supporting document 6.3, the Health Research Authority Confidentiality Advisory Group (HRA CAG) letter of support dated the 6th January 2021, where it stated *"The applicants confirmed intentions to retain pseudo-anonymised information for 15 years, with the linkage key held by NHS Digital"*; and asked that confirmation was provided as to how the University of Oxford would transition away from holding identifiers, noting NHS Digital would continue to hold the linkage key. IGARD had a lengthy discussion in relation to NHS Digital data that had already flowed for cohort members using consent as the legal basis, given that consent was no longer judged adequate and had been supplanted by s251. IGARD queried if the University of Oxford had the relevant support to continue to hold the data previously disseminated for those individuals with National Data Opt-outs (NDOs), given that the NDO is typically applied where s251 is the

	legal basis. IGARD therefore asked that the applicant queried this with HRA CAG; and that once a response had been received, asked that section 1 (Abstract) and section 5(a) were updated for transparency. IGARD also asked that a copy of the response from HRA CAG was uploaded to NHS Digital's Customer Relationship Management (CRM) system for future reference. IGARD noted the statement in section 5(b) that participants who *"…have decided that they do not wish their data to be used in this study will be able to opt out."*, and noting that the reference to 'opting out' could be confused with the NDO, asked that for clarity, this reference was amended to refer to participants *"withdrawing consent to participate in the study"*. IGARD queried the statement in section 5(a) *"Participants who consented to have their medical records followed up also consented to providing blood samples for the genomic arm of this study… This will involve sending pure DNA samples"*. IGARD expressed concern that the blood samples provided by participants in 2007 – 2010, appeared to be being processed without further specific consent; or if consent had been taken for the assays, whether the consent taken at the time covered the dramatically different technology available in the present day. IGARD queried if this specific point had been discussed with the Research Ethics Committee (REC). IGARD acknowledged that whilst no formal guidance in respect of this has been issued by relevant bodies, they, and many other commentators, were of the view that genetic data may be considered 'personal data' under UK GDPR (**not** anonymous), see for example the ICO commissioned analysis by the PHG Foundation. In addition, IGARD queried if the outputs from the DNA analysis carried out on the blood samples previously provided by participants, would be linked with the NHS Digital data; and asked that this was clarified in section 5(a). IGARD suggested, that given the long running nature of the study and projected work into 2035, the applicant should consider setting up a patient and public involvement (PPI) group, to discuss future plans, including, but not limited to, further research in respect of the blood samples provided by participants. IGARD noted the patient and public involvement and engagement (PPIE) on the website and the protocol, that had been undertaken with members of the public on similar studies, and suggested that the applicant gave further consideration to actively involving participants, and in line with the HRA guidance on Public Involvement. IGARD noted the global impact of the study, however advised that the application was predominantly silent on the benefits of the study to date, as summarised on the study website. IGARD asked that section 5(a) and section 5(d) (Benefits) were updated with a brief lay summary / bullets outlining the benefits of the study and in line with NHS Digital's DARS Standard for Objective for Processing and NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted that Section 5(d) (iii) (Yielded Benefits) did not appear to be in line with the NHS Digital DARS Standard for Expected Measurable Benefits and asked that this section was updated. In addition, asked that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii) and to ensure these are clear about the benefits to both patients and the health care system more generally. IGARD queried the item numbered *"6"* in the yielded benefits in section 5(d) (iii) relating to ischaemic strokes, and asked that this was updated with further clarification on this point, so that the benefit is understandable to a lay reader; and in line with NHS Digital DARS Standard for Expected Measurable Benefits.

	IGARD noted a number of acronyms in section 5, and asked that this public facing section, that forms NHS Digital's data uses register, 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 *"HRA CAG"*. IGARD queried the statement in section 5(a) *"Further data releases will allow the study team to continue follow up into the extremely long term."*, and asked that this was updated to a more precise description, for example *"entire lifespan including cause of death".* IGARD queried the statement in section 1 *"…the special condition does not include instruction to destroy the data in light of current guidance pending the Covid-19 enquiry [sic]."*. NHS Digital advised IGARD that as per the current (NHS Digital) advice, there was currently a pause on the destruction of NHS Digital data, in light of the forthcoming public COVID-19 inquiry. IGARD noted the verbal update from NHS Digital, however suggested that the blanket cessation of destruction of data may not be the best course of action in all cases, for example, noting that this study was not connected in any way related to COVID-19 and that the UK General Data Protection Regulation (UK GDPR) principles still applied. 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. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from Data Access Request Service (DARS) in due course. IGARD suggested that the applicant may wish to consider the NHSBSA Medicines Dispensed in Primary Care dataset. IGARD noted that all necessary approvals would need to be in place from HRA CAG, before the dissemination of this data; and that should the applicant wish to amend this Data Sharing Agreement (DSA) to receive the data, then the application would need to be updated. IGARD asked that if the NHSBSA dataset **was** required, noting the constraints placed in the Direction for the collection of NHSBSA dataset, specifically *"Providing intelligence about the safety and effectiveness of medicines…"*; that section 5(a) was updated, to align with the scope of the Direction to ensure that the objectives, processing and outputs are permitted uses of the data. In addition, IGARD also asked, that a special condition was inserted in section 6 (Special Conditions), that any use of the NHSBSA dataset must be within the parameters of the relevant Direction authorising that collection. IGARD advised that they would wish to review this application when it comes up for amendment, to ensure continued alignment with the HRA CAG specific conditions of support (with the exception of the inclusion of the NHSBSA dataset). **Outcome:** recommendation to approve The following amendments were requested: 1. To provide a description in section 5(a) and section 5(b), of any current or planned pooling of data or combination of processing with NIC-147885-0TV66 and NIC-148341-TC6TD. 2. To provide a brief explanation in section 5 as to why the data is treated as *"identifiable"*, as per the verbal update from NHS Digital. 3. In respect of the identifiers:

a) To provide confirmation in section 5 as to why the University of Oxford are continuing to hold identifiers.
b) In line with the HRA CAG support, to provide confirmation how the University of Oxford will transition away from holding identifiers, (noting NHS Digital will continue to hold the linkage key.

4. In respect of the NDO:
   a) The applicant to confirm with HRA CAG: where NHS Digital data has already flowed for cohort members who have subsequently exercised the NDO, do they have support to continue to hold the previously disseminated data for those individuals?
   b) To update section 1 and section 5(a) to reflect the response from HRA CAG for transparency.
   c) NHS Digital to upload a copy of the HRA CAG confirmation on to their CRM system for future reference.
5. For the avoidance of any confusion with the NDO, to amend the reference in section 5(b) that participants *"…will be able to opt out"*, to refer to participants "*withdrawing consent to participate in the study*".
6. To state in section 5(a) whether or not the outputs from the DNA analysis carried out on blood samples provided by participants previously, will be linked with NHS Digital data.
7. Noting the global impact of the study, to update section 5(a) and section 5(d) with a brief lay summary / bullets outlining the benefits of the study. This summary could be directly copied over from the study website.
8. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout, to ensure acronyms be defined upon first use, for example *"HRA CAG"*.
9. 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 approach is supported by advice on this point from PTE.
10. To update the reference in section 5(a) from *"…extremely long term"* to a more precise description, for example *"entire lifespan including cause of death".*
11. 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 global high impact, to provide 2 or 3 specific yielded benefits accrued to date.
    c. To provide further clarification on the yielded benefits relating to ischaemic strokes so that the benefit is understandable to a lay reader.

The following advice was given:

1. IGARD suggested, that given the long running nature of the study and projected work into 2035, the applicant should consider setting up a PPI group, to discuss future plans, including (but not limited to) further research in respect of the blood samples provided by participants.
2. IGARD noted the PPIE on the website and the protocol, that had been undertaken with members of the public on similar studies, and suggested that the applicant gave further consideration to actively involving participants, and in line with the HRA guidance on Public Involvement.
3. IGARD noted the narrative in the abstract and the verbal update from NHS Digital in respect of the current guidance from NHS Digital in respect of pausing the destruction of data, in light of the forthcoming public COVID-19 inquiry. IGARD suggested that the

	blanket cessation of destruction of data may not be the best course of action in all cases, for example, noting that this study was not connected in any way related to COVID-19 and the UK GDPR principles still applied. 4. IGARD suggested that the applicant may wish to consider the NHSBSA Medicines Dispensed in Primary Care dataset. IGARD noted that all necessary approvals, would need to be in place from HRA CAG, before the dissemination of this data. Should the applicant wish to amend this DSA to receive the data, then the application should be updated as follows: a. To update section 5(a) and in line with NHS Digital's DARS Standard for Objective for Processing, when referencing processing of NHSBSA dataset to ensure a clear narrative is provided linking the purposes to the relevant Direction. b. To insert a special condition in section 6, that any use of the NHSBSA dataset must be within the parameters of the relevant Direction authorising that collection. 5. IGARD advised that they would wish to review this application when it comes up for amendment (with the exception of the inclusion of the NHSBSA dataset), to ensure continued alignment with the HRA CAG specific conditions of support. **Risk Area:** IGARD expressed concern that the blood samples provided by participants in 2007 – 2010, appeared to be being processed without further specific consent (or if consent had been taken for the assays, whether the consent taken at the time covered the dramatically different technology available in the present day). IGARD queried if this specific point had been discussed with the REC. IGARD acknowledged that whilst no formal guidance in respect of this has been issued by relevant bodies, they, and many other commentators, were of the view that genetic data may be considered 'personal data' under UK GDPR (**not** anonymous), see for example the ICO commissioned analysis by the PHG Foundation.
3.4	University of Oxford: MBRRACE-UK - Delivering the National Maternal, Newborn and Infant Clinical Outcome Review Programme - National Surveillance of Maternal and Perinatal Deaths (Presenter: Denise Pine) NIC-359651-H3R1P-v5.4 **Application:** This was an amendment to add NHS England as a joint Data Controller. 'Mothers and Babies: reducing Risk through Audits and Confidential Enquires across the UK' (MBRRACE-UK) is the collaboration appointed by the Healthcare Quality Improvement Partnership (HQIP) to run the national Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP), which continues the national programme of work conducting surveillance and investigates the causes of maternal deaths, stillbirths and infant deaths. The aim of the MNI-CORP MBRRACE-UK programme is to provide robust national information to support the delivery of safe, equitable, high quality, patient-centred maternal, newborn and infant health services. MBRRACE-UK will link NHS Digital data with statutory birth, stillbirth and infant death notification data supplied by the Office for National Statistics (ONS). The study is relying on s251 of the NHS Act 2006, for the flow of data out of NHS Digital. NHS Digital advised IGARD that section 1 (Abstract) of the application stated that the application was an *"amendment and renewal"*, however confirmed that this was incorrect and would be updated to reflect that it was an *"renewal"* only. NHS Digital noted that section 1(b) (Data Controller(s)) stated that NHS England's Data Sharing Framework Contracts (DSFC) was due to expire on the 8th November 2021; however confirmed that following submission of the application for IGARD to review, this had been updated to reflect the new expiry date.

	Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) meeting on the 14th June 2016. IGARD noted the verbal update from NHS Digital, in respect of the application being submitted for an 'renewal' and not an amendment, and supported the relevant updates to the application to reflect this. IGARD noted and commended NHS Digital, on the quality of the information provided within section 1, which supported the review of the application by Members. 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 noted that section 3(b) (Additional Data Access Requested) stated that access would be for identifiable notification data for all births, however supporting document 4.6, the Health Research Authority Confidentiality Advisory Group (HRA CAG) register, under *"Description of confidential patient information used"*, stated that the cohort only covered maternal deaths, maternal morbidity, late foetal losses, late terminations, stillbirths, neonatal deaths and perinatal morbidity and mortality, therefore excluding healthy births. NHS Digital advised that the s251 support included the provision of birth data for all babies, and that the HRA CAG register summary stated the following *"In order to calculate rates we also receive and process identifiable denominator data for stillbirths, infant deaths, live births and maternal deaths from the Office for National Statistics for England and Wales 1st January 2009 onwards.* ***We also receive and process identifiable data from the NN4B system for stillbirths and live births 1st January 2013 to 31st December 2014 and from the system replacing NN4B from 1st January 2015****."* IGARD noted the verbal update from NHS Digital and confirmed that they were content that live births were covered as part of the HRA CAG support. NHS Digital noted that in respect of the amendment to the application, to add NHS England as a joint Data Controller, senior colleagues within the Data Access Request Service (DARS), had suggested that other legal entities may also need to be added, due to the merger between NHS England and NHS Improvement (Monitor and the NHS Trust Development Authority (TDA)). IGARD noted the update from NHS Digital, and agreed with the suggestion made by DARS colleagues, in that if employees of NHS Improvement (Monitor and the NHS Trust Development Authority (TDA)), were carrying out data controllership activities, then they would also need adding to the Data Sharing Agreement (DSA). IGARD therefore asked, in line with NHS Digital's DARS Standard for Data Controllers, that the applicant clarified 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); and that the application was updated as necessary to reflect the factual scenario. IGARD queried the references in section 5 (Purpose / Methods / Outputs) to *"Personal Demographic Services (PDS)"* data, and noted that although Birth Notification Data, was derived from the PDS dataset, this could cause confusion when reading the application; and asked that references to *"PDS"* were removed from section 5 and replaced with *"Birth Notification Data"*, as per section 3 (Datasets Held / Requested). IGARD noted the reference in section 5(a) (Objective for Processing) to *"patient[s]"*; and asked that to reflect current usage, these references were *removed,* and instead replaced with, "*women and person centred care*", or similar, to both avoid suggestions of medicalising childbirth and to ensure inclusivity.

	IGARD noted the references in section 5 to 'ethnicity' data, however asked that this was updated for transparency, to clarify that this particular dataset was not always complete / accurate, but was currently the best available data from NHS Digital. IGARD queried the references in section 5 to women with 'high-risk ethnicity', and asked that this was updated to more accurately refer to *"women who are put at risk because of their ethnicity"*. IGARD noted the helpful definitions outlined in section 5(d) (Benefits), for example, in relation to late miscarriages and perinatal deaths; and asked that this was replicated in section 5(a) for ease of reference / understanding. IGARD noted the significant volume of data requested, asked that in line with NHS Digital DARS Standard for Expected Measurable Benefits the applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii) (Yielded Benefits) and to ensure these are clear about the benefits to both patients and the health care system more generally. IGARD queried the benefits outlined in section 5(d), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edit to only leave examples that reflect the benefits to Health and Social Care System, in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted that section 5(d) included a rationale for the programme, and noting that this was not the most appropriate place for this information, asked that this was removed and added to section 5(a). IGARD noted that although there was a lot of information in the yielded benefits in section 5(d) (iii), key information such as quantitative outputs had been omitted, and asked that this was updated with information including, but not limited to, the percentage reduction of stillbirths, and in line with NHS Digital DARS Standard for Expected Measurable Benefits. IGARD noted supporting document 6, the patient poster, that had been provided; however noting the poster was dated 2016, suggested to the applicant, that the text was reviewed by both their patient and public involvement (PPI) group and by the appropriate subject matter experts to ensure it met UK General Data Protection Regulation (UK GDPR) requirements, and ensure it used appropriately inclusive language, for example, replacing the reference to only *"Mothers"* being able to withdraw their baby's data to make clear that anyone with parental responsibility could do so. NHS Digital told IGARD the applicant had only received two withdrawal requests which, given the number of births every year, struck IGARD as surprisingly small; and therefore asked that MBRRACE-UK updated Health Research Authority Confidentiality Advisory Group (HRA CAG) on the number of withdrawal requests and consider whether those with parental responsibility were aware of the programme. IGARD noted and commended the involvement of the PPI stakeholder group, in the design of the patient poster and suggested that, in light of the outcomes of the previous MBRRACE reports, that the applicant ensured that representatives from the most affected communities are represented in the stakeholder group. **Outcome:** recommendation to approve subject to the following condition: 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. The following amendments were requested: 1. To remove reference to *"PDS"* in section 5 and replace with *"Birth Notification Data"*, as per section 3. 2. To reflect current usage, to amend section 5(a) to remove references to *"patient[s]"*and instead refer to "*women and person centred care*", or similar, to both avoid suggestions of medicalising childbirth and to ensure inclusivity. 3. To update section 5 to clarify that where the ethnicity data is referenced, that this dataset is not always complete / accurate, but is the best available data from NHS Digital. 4. To update section 5 to amend the references from women with high-risk ethnicity, to *"women who are put at risk because of their ethnicity"*. 5. In respect of the benefits and in line with NHS Digital DARS Standard for Expected Measurable Benefits a) To replicate the definitions from section 5(d) in section 5(a). 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. c) To remove any specific outputs from section 5(d) and move to section 5(c). d) To remove the rationale for the programme from section 5(d) to section 5(a). e) To update the yielded benefits, with some quantitative outputs, including (but not limited to), the percentage reduction of stillbirths. The following advice was given: 1. IGARD noted that the poster provided as a supporting document was dated 2016, and suggested the text was reviewed by both their PPI group and by the appropriate subject matter experts to ensure it meets UK GDPR requirements and ensure it uses appropriately inclusive language, for example, replacing the reference to only *"Mothers"* being able to withdraw their baby's data to make clear that anyone with parental responsibility could do so. 2. IGARD noted and commended the involvement of the PPI stakeholder group, in the design of the poster and suggested that, in light of the outcomes of the previous MBRRACE reports, that the applicant ensure that representatives from the most affected communities are represented in the stakeholder group. 3. MBRRACE-UK to update HRA CAG on the number of withdrawal requests and consider whether those with parental responsibility are aware of the programme. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.
4 **4.1**	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent 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). Group Application[1]: DSfC - STP - NHS Staffordshire and Stoke on Trent CCGs - Comm NIC-234915-J3K4V-v2.2

[1] NHS North Staffordshire CCG, NHS East Staffordshire CCG, NHS South East Staffordshire and Seisdon Peninsula CCG, NHS Stoke on Trent CCG, NHS Stafford and Surrounds CCG and NHS Cannock Chase CCG

	This application was for a renewal and amendment to 1) add Optum Health Solutions UK Limited for the purpose of commissioning, 2) add Amazon Web services who provide cloud services to Optum, 3) expand the use of Microsoft Azure Cloud to Optum, 4) add medicines dispensed in primary care (NHSBSA) and adult social care data, 5) enable linkage to GP data. The purpose of the data request is to provide intelligence to support the commissioning of health services. This application was seen at the IGARD business as usual meeting on the 21st October 2021, IGARD did not review the application or any supporting documentation due to the fact that the documentation had not been provided timely, but made a positive statement of support with regard to the linkage to GP data for the purpose of **commissioning only**. IGARD noted that on the 22nd October 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the above Data Sharing Agreement, had been progressed, via the SIRO Precedent. IGARD noted and thanked NHS Digital for the written update, however advised that the decision taken by the SIRO was based on a verbal update from NHS Digital following the meeting, and may not be reflective of the written outcomes that were disseminated as per process following the meeting, and subsequently published in the minutes from the 21st October 2021.
4.2	<u>Carnall Farrar**:** Application for Carnall Farrar to access NHS Digital data, to permit more detailed insights into the needs of the population and the challenges facing the system when shaping clinically and financially sustainable health and social care services across England. NIC-243790-Y8K8C</u> The purpose of this application was for controlling the conditions of data aggregation, perform bench-marking analysis as well as specific demands of the NHS stakeholders, to allow them to make effective decisions based on the most up-to-date information. This application was seen at the IGARD business as usual (BAU) meeting on the 26th September 2019, where IGARD had made a recommendation to approve, with a number of amendments, including: 1. To add a special condition in section 6 stating that a report will be provided to NHS Digital in 12-months; including (but not limited to) how many NHS organisations the applicant is working for as a result of receiving this data and examples of work done demonstrating the requirement for the extent of data provided. IGARD noted that on the 22nd October 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the special condition had not been met, and there was ongoing work with the applicant in respect of this outstanding special condition. NHS Digital confirmed that the SIRO had agreed to authorise an extension and renewal with a special condition that the updated report must be supplied by no later than 28th February 2022. In addition, NHS Digital have confirmed that the next iteration (including the report) would be presented at a future IGARD BAU meeting. IGARD noted and thanked NHS Digital for the written updates and asked that confirmation was provided in March 2022 that the report had been received by NHS Digital, noting that failure to submit this would be a breach of the Data Sharing Agreement.
5	<u>Oversight & Assurance</u>

5.1	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. IGARD agreed, that from the 22nd July 2021, where substantial issues / significant risks are raised in respect of the returning applications, that a high-level summary of these points would be included within the published minutes for transparency and audit purposes: • **NIC-204580-F5B0C Cheshire & Merseyside Cancer Alliance** - IGARD noted that the Yielded Benefits did not appear to have been updated in line with NHS Digital's DARS Standards for Expected Measurable Benefits. • **NIC-337801-K2N5Y Health & Safety Executive** - IGARD noted that as per usual process, they had not been notified that this application had progressed via the SIRO precedent, so that it could be captured in published BAU minutes for transparency. • **NIC-351522-Y6W3L Health & Safety Executive** - IGARD noted that as per usual process, they had not been notified that this application had progressed via the SIRO precedent, so that it could be captured in published BAU minutes for transparency. • **NIC-433629-H3M0G NHS England** - IGARD requested an update under a future AOB item, as to why this new application had been progressed under the NHS Digital SIRO precedent, since it was not clear within the application and supporting documentation. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including SIRO Precedent, due to the fact that this was a new application that progressed under Precedent. • **NIC-147923-P5DTX Institute of Cancer Research** • **NIC-147748-XD18S Institute of Cancer Research** • **NIC-147749-3SSRF Institute of Cancer Research** • **NIC-454889-G1L1V Genomics PLC** IGARD welcomed the eight applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report. 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 – see item 5.2 below 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.
5.2	<u>Deep Dive request for IG release 00517</u> IGARD noted that the IG Release 00517, NHS National Services Scotland (NSS) / Public Health Scotland had been circulated and was in the process of being reviewed out of committee by members. IGARD noted that the comments that would be shared with the Privacy, Transparency and Ethics Directorate and a summary of the points raised included under this section in the coming weeks.

6	COVID-19 update 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 due to conflicting priorities for IGARD members and the IGARD Secretariat, the COVID-19 response meeting on Tuesday, 2nd November 2021 was cancelled.
7 **7.1**	AOB: NIC-364245-C8C6X University of Oxford This application was presented at the IGARD business as usual meeting on the 23rd September 2021, where IGARD recommended to approve with conditions, amendments and advice. IGARD noted that on the 25th October 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the applicant had confirmed that they no longer wished to proceed with the Data Sharing Agreement, and this had therefore been cancelled. IGARD noted and thanked NHS Digital for the written update, however noting that this does not happen very often, queried the reason for the withdrawal noting the public money spent progressing the application; and advised NHS Digital that they would welcome additional information on this.
7.2	COVID-19 Public Inquiry IGARD noted that as referred to in items 3.1, 3.2 and 3.3, NHS Digital were in the process of preparing for the COVID-19 public inquiry, and asked that they were kept up to date with any processes that they needed to be aware of / take responsibility for in terms of retaining information (noting IGARD members accessed information relating to IGARD via their individual NHS accounts). 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 29/10/21

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)
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