Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 31 October 2019

In attendance (IGARD Members): Maria Clark, Kirsty Irvine (Chair), Eve Sariyiannidou, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Garry Coleman (item 3), Arjun Dhillon, James Humphries-Hart, Dickie Langley (item 3 and AOB), Kimberley Watson (item 3 and AOB), Vicki Williams.

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

Observers: Abisola Atoyegbe (items 1-3), Victoria Byrne-Watts (item 2.2), Katerina Michala (items 1-3)

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 17th October 2019 IGARD meeting were reviewed and, subject to a number of minor amendments, were agreed as an accurate record the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix B).
2	**Data applications**
2.1	University College London: MR1362: Extension of NIC-349413-F1J1N - Next Steps Cohort Study (Presenter: Stuart Blake) NIC-15226-X7Z9R **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) data and an amendment to add MRIS mortality and embarkation data; as well as the addition of Copyprint UK Limited as a Data Processor. The Next Steps Longitudinal Study of Young People in England (LSYPE) is an established longitudinal study which has followed the lives of 15,620 people born in 1989/90, since year 9 of secondary school. Information was collected from cohort members on many aspects of their lives such as education, employment, health and well-being, relationships and family life, housing and finances, social participation and attitudes. Data collection focused on young people's transitions into further/higher education and the labour market or to other outcomes, such as parenthood. The application was been previously considered on the 13th June 2019 when IGARD had deferred making a recommendation pending: to update the application to ensure one legal basis is put forward and justified under GDPR; in respect of the s251 support which appears to be for 'date of death', to provide relevant evidence that 'cause of death' is a supported field; in respect of the cohort, to clarify: a) who is in the cohort; b) whose data is being tracked and obtained by this agreement; and c) that the data for those who have withdrawn from the study / cohort are not being accessed via this agreement; to provide an explanation of any discrepancies between the description of the cohort in SD10 and the application and provide a clear and coherent narrative which is consistent to the cohort numbers throughout the application; to amend the fair processing notice to ensure it is GDPR compliant including (but not limited to) to specifically state that identifiers are sent to NHS Digital for the purpose of tracking and to clarify that tracking is through NHS Digital; to update section 4 to clearly state

	the applicant's fair processing notice 'does not' meet the NHS Digital's fair processing criteria for privacy notices; to update section 5(b) to amend the "subcontractor" reference to "Copyprint UK Limited"; to provide clarification and an explanation of what data the UK Data Service will obtain under this application and in what format; to update section 5c and 5d to clearly outline the societal impact; to update section 5(d) to remove reference to the named MP; to amend the application to remove the references to "anonymised" data and replace with "pseudonymised" data. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD noted in section 1 (Abstract) that although a legal basis for university College London (UCL) had been inserted, it should be updated to include the full standard wording justification for the General Data Protection Regulations (GDPR) legal basis put forward for UCL. It was noted that the applicant had updated sections 5(c) (Specific Outputs Expected) and 5(d) (Benefits) to include additional information, however section 5(d) (Yielded Benefits) should provide a clearer link between the research projects outlined and the benefits accruing. IGARD queried the special condition in section 6 (Special Conditions) starting "*This agreement is an interim measure to permit the retention of data for a short period...*" and suggested that it be removed since it was no longer relevant to this application. **Outcome Summary:** recommendation to approve. The following amendments were requested: 1. To update section 1 (Abstract) to include the full standard wording for the GDPR legal basis for UCL. 2. To amend section 5(d) (Yielded Benefits) to provide a clear link between the research projects outlined in section 5 and the benefits accruing. 3. To remove the special condition in section 6 starting "*This agreement is an interim measure to permit the retention of data…*", since it is no longer relevant.
2.2	<u>London School of Hygiene and Tropical Medicine: (MR1355) The Manchester and (MR1016) ARTISTIC Cohorts (HPV and Cervical Cancer) (Presenter: James Humphries-Hart) NIC-58603-S6Z1B</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) and an amendment to join two cohort studies (The Manchester Cohort Study NIC-58603-S6Z1B and The ARTISTIC Trial Cohort Study NIC-226323-X4L5B) and merge into one Data Sharing agreement (DSA) in order to streamline processing activities and analysis. The objective for the two cohorts is to study the long-term risk of cervical cancer and cervical pre-cancer following Human Papilloma Virus (HPV) infection. The Manchester Cohort Study participants were recruited between 1987-1993 and The ARTISTIC Trial Cohort Study participants were recruited between 2001-2004. Both studies targeted the same Greater Manchester area with the aims for both to study the same subject: HPV. The questions this research aims to influence are: Is it safe to leave a longer interval between screening tests when a woman has a negative HPV test?; What follow-up tests should be done in women who test positive for HPV? The study can evaluate cytology, genotyping (identifying the strain of HPV) or new testing methods; what age is it safe to stop screening? **Discussion:** IGARD welcomed the application and noted with interest that in March 2019 Public Health England (PHE) launched the first ever national cervical screening promotion campaign "*Cervical Screening Saves Lives*" noting that the aim of the PHE campaign was to raise awareness of the risks of cervical cancer and highlight the preventative benefits of

	screening to improve attendance across England. IGARD reflected that a benefit that was not fully articulated in the application was that for some women an alternative to this invasive screening procedure would be welcome to support that particular group of women accessing screening services; either by a reduction in the number of attendances for the procedure or testing for HPV at an earlier stage in order to encourage women to attend cervical cancer screening. It was suggested that a paragraph be included at the start of section 5(a) (Objective for Processing) to clearly explain why a possible reduction in the frequency of cervical smears (smear test) was in the public interest despite the PHE publicity surrounding perceived benefits in increased cervical screening; to clearly explain how a reduction in frequency of cervical screening may be of particular benefit to those women who avoid such invasive procedures; to give a clear background to the introduction of HPV screening which was an outcome of earlier studies; and to give further detail (as outlined in the study protocol) of the benefits of the study to secondary outcomes e.g. other gynaecological cancers. In addition, it was suggested that the bullet points in section 5(d) (Benefits) under the title "*the expected impacts of the research on the NHS and public include…*" be reordered so that the benefits to women came before projected savings to the NHS budget, since the study was about the promotion of health and benefits to the public, not just about reducing cost. IGARD noted that when this application had been previously presented to its predecessor the Data Access Advisory Group (DAAG) on the 16 August 2016, the application had been presented under NIC-226323-X4L5B, however NHS Digital noted that this was later found to be an error and that the correct NIC number was NIC-58603-S6Z1B. The approval route through NHS Digital for The Artistic Trial Cohort Study limb (NIC 226323) was not clear and IGARD asked that documentary evidence be provided of the approval route, including any issues the application may have brought up including, but not limited to, Data Controllership. IGARD noted that the supporting document provided (SD6 – The ARTISTIC Protocol 23 March 2017) detailed the researchers involved in the study design and outputs, including a researcher based at the University of Manchester. It was not clear why the University of Manchester was not considered a joint Data Controller since a key member of the research team was listed in the protocol as being based at the University and suggested that a clear narrative be provided as to why the University was not considered a joint Data Controller, in light of the information provided. IGARD were unclear as to why such a seemingly "substantial amendment", the merging of two cohort applications into one application, did not warrant an ethics review and asked that either updated ethics support for the combined studies be provided or written confirmation from the Research Ethics Committee (REC) be provided that the combination of the two studies was not considered a "substantial amendment" requiring updated ethics support. The aged ethics documentation was also noted and IGARD asked that if the ethical support did not need to be refreshed on the basis of a "substantial amendment" that REC provided written confirmation that the ethics support did not need to be refreshed due to the time that elapsed since the original REC reviews (The Manchester Cohort Study REC approval date 2013 and the ARTISTIC Trial Cohort Study REC approval date 2014). IGARD also noted that ethics approvals were conditional on the approval for research to be carried out on NHS sites and asked that written confirmation be provided by REC that the conditions of ethics support had been met, whether using new REC support of using the 'old REC support'. IGARD noted that the Health Research Authority Confidentiality Advisory Group (HRA CAG) support for The Manchester Cohort Study, particularly supporting document 1.2 (ECC 5-05 J 2012 CAG RAH Approval May 2015) noted that "*Patients would be flagged for 20 years…*"

	however it was not clear if the 20 years started from the point of recruitment to the study or from the date of HRA CAG support and asked for written clarification of this point. In addition, IGARD asked that a copy of the HRA CAG register, via a screen shot, be provided detailing CAG approval and that this document be also uploaded to NHS Digital's Customer Relationship Management (CRM) system as evidence of such support for the Manchester Cohort Study. IGARD also noted that in relation to the HRA CAG support for The ARTISTIC Trial Cohort Study that a copy of the HRA CAG register, via a screen shot, be provided detailing CAG approval and that this document be also uploaded to NHS Digital's CRM system as evidence of such support. It was also noted that for HRA CAG support to be valid for both The Manchester Cohort Study and The ARTISTIC Trial Cohort Study, that REC support should be in place and unconditional and IGARD noted the queries raised earlier in the discussion surrounding the REC support. IGARD noted that the Privacy Notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that since this was a longitudinal study that the applicant take steps to comply with General Data Protection Regulations (GDPR). IGARD suggested that as part of the website review, use of language was considered such as changing the reference from "*management of women with…*" to "*managing conditions…*". In respect of The Manchester Cohort Study, that those women in particular be given the opportunity to opt out, which is a standard condition of support from HRA CAG, and that consideration be given of how to publicise the ongoing study across the Greater Manchester geographical area where the women were recruited, such as publicity in GP Practices or women's health clinics in hospitals in the Greater Manchester area. It was also suggested that language used in section 5(b) (Processing Activities) be updated to reflect the current approach to speaking to and about patients: such as amending "*control women*" to "*women in the control group*" IGARD welcomed the applicant's engagement with the wider community including the team's aim to work with Jo's Cervical Cancer Trust and / or the Eve Appeal, but suggested that a more concrete plan for the involvement of these two cervical cancer charities be included with the steps outlined for engagement with the cohort and wider community, given the large cohort and reliance by the researchers on s.251 support. It was also noted that the projected dates listed in section 5(c) (Specific Outputs Expected) for the publications and conference presentations be reviewed to reflect a more realistic timeframe. **Outcome Summary:** recommendation deferred, pending: 1. To insert in section 5(a) a paragraph clearly explaining: a. why a reduction in smear test screening frequency is in the public interest despite the publicity surrounding the perceived benefit in increased smear test screening. b. how a reduction in smear test screening frequency may be of particular benefit to some women who avoid such invasive testing. c. the background to the introduction of HPV screening which was an outcome of earlier studies. d. the further detail contained in the protocol relating to the benefits of the study to secondary outcomes e.g. other gynaecological cancers 2. To clearly explain why the University of Manchester is not considered a joint Data Controller since a key member of the research team is outlined in The ARTISTIC Trial Cohort Study protocol as being based at that University.

3. Ethics:
    a. to either provide updated ethical support for the combined studies due to substantial amendments made, or to otherwise provide written confirmation that the combination of the two studies does not constitute a "substantial amendment" requiring updated support.
    b. In addition, if the ethical support does not need to be refreshed on the basis of "substantial amendment", to provide written confirmation that the ethics support does not need to be refreshed due to the time elapsed since the original REC reviews.
    c. With regard to either new REC support or if using the "old REC support", that in either case, to confirm that the condition of ethics support has been met with regard to approval for the research to be carried out on NHS sites.
4. HRA CAG support for The Manchester Cohort Study:
    a. To provide a copy of the HRA CAG register (via a screen shot) and to upload an updated copy to the CRM holder.
    b. To provide written clarification when the 20-year period of flagging, referred to in the HRA CAG letter of support, started for The Manchester Cohort Study (such as from the point of recruitment to the study or from the date of HRA CAG support).
    c. REC support should be in place and unconditional for the HRA CAG support to be valid (see point 3 above).
5. HRA CAG support for The ARTISTIC Trial Cohort Study:
    a. To provide a copy of the HRA CAG register (via a screen shot) and to upload an updated copy to the CRM holder.
    b. REC support should be in place and unconditional for the HRA CAG support to be valid (see point 3 above).
6. Fair Processing:
    a. The website could be updated with current approach to language such as changing reference from "*management of women with…*" to "*managing conditions*"
    b. In respect of The Manchester Cohort Study in particular, the women in that cohort should be given the opportunity to opt out (which is a standard condition of HRA CAG support) and consideration given how to publicise the ongoing study to give effect to this; such communications may be via publicity in GP practices, or women's health clinics in the local hospital in the geographical area the women were recruited.
7. Section 5(c) to be updated, if possible, to reference a more concrete plan for the involvement of the Jo's Cervical Trust and / or the Eve Appeal (both cervical cancer charities) with steps for engagement with the cohort and the wider public (particularly important with regard to the large cohort and the fact that the researchers are relying on s251 support).
8. To update the projected dates of publication and conference presentations within section 5(c) with a more realistic timeframe.
9. To reorder the bullets in section 5(d) under "*The expected impact of the research on the NHS and public include…*", so that the benefits to women come before the projected cost savings.
10. To provide documentary evidence of the approval route through NHS Digital for The ARTISTIC Trial Cohort Study limb (NIC-226323) and any issues that application may have brought up, including Data Controllership.

2.3	University College London: Centre for Longitudinal Studies Next Steps Data Linkage: Next Steps Age 25 Study (Presenter: Dickie Langley) NIC-51342-V1M5W **Application:** This was an amendment application to include a sub-licensing model to the current Data Sharing Agreement (DSA). No new data is being requested under this application. The purpose is for a longitudinal study following the lives of 16,000 people born in 1989-90 and forms part of a collection of UCL studies (1958 National Child Development Study, 1970 British Cohort Study and the Millennium Cohort Study). This study is to map the cohorts' journey through education, employment, economic circumstances, family life, physical and emotional wellbeing, social participation and attitudes, and focuses on young people born in the early 1990s and their pathways through their teenage years and their transitions into adulthood and the labour market. The study has already been highly valuable in informing policy decisions and enhancing understanding of how specific Government policies can influence and shape the lives of young people. The application was been previously considered on the 13th June 2019 when IGARD had deferred making a recommendation pending: to amend the application throughout to address the following points from the 'Sub-Licencing and Onward Sharing of Data' Standard: Point 3, Point 5d, Point 5e and Point 6; to confirm within section 5(a) that there will be no charge for the sub-licensing; to update section 1 to reference that data is being supplied by NHS Digital under the NHS Digital Fair Processing Assessment in point 7; and to update section 5(d) to remove reference to the named MP and replace with a more generic statement of use. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. It was noted that since this was a live application with a Data Sharing Agreement (DSA) in place, IGARD were specifically looking at the sub-licencing aspect of the application presented and it was suggested that section 5(a) (Objective for Processing) include the history of the application in order to set the scene including clearly articulating that this amendment was for the sub-licencing aspect only. IGARD noted that since there was no identifying data in section 3 (Datasets Held / Requested) that a clear narrative be inserted into section 1 (Abstract) to clearly explain that the legal basis of consent was for the initial linkage of the identifiers with the Centre for Longitudinal – University College London (CLS-UCL) data and that for this particularly application there was no reliance on consent as a legal basis to flow the pseudonymised data to the sub-licensees. IGARD noted that since this was an aged application that had been previously recommended for approval by its predecessor the Data Access Advisory Group (DAAG) on the 31 January 2017, that IGARD would wish to review this application again when it comes up for renewal, and before August 2020. It was noted that the suite of documents provided for IGARD's review contained a number of obsolete references, for example ONS accredited research and the micro data release committee, and suggested that these references be removed and replaced with the equivalent standards and protections. IGARD noted that some of the acronyms within the application were not always defined upon first use and suggested the application be amended as necessary to make this clear, including but not limited to reference to "DAC approval". **Outcome Summary:** recommendation to approve The following amendments were requested:

	1. To insert in section 1 (Abstract) a clear narrative explaining that the legal basis of consent, referenced in section 3, is for the initial linkage of identifiers with CLS-UCL data and that there is no reliance on consent as a legal basis to flow pseudonymised data to the sub-licensees. 2. To review the suite of sub-licensee documentation and remove any obsolete references (for example ONS accredited researchers, micro data release committee) and ensure the obsolete references are replaced with equivalent standards and protections. 3. To insert at the start of Section 5(a) a clear narrative of the history of the application to set the scene, clearly articulating this is an amendment for the sub-licencing aspect only. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal
3	Oversight & Assurance: 5e Commercial Standard and Commercial applications (Presenter: Garry Coleman) The Associate Director Data Dissemination, Garry Coleman, attended IGARD to discuss with members the Commercial Standard (5e) and commercial applications in general. It was agreed that a workshop be put in place to update the relevant artefacts owned by DARS in order to support both NHS Digital and the customer.
4	Oversight & Assurance: Secondary Use and Direct Care (Presenters: Dickie Langley / Kimberley Watson) NHS Digital noted that the National Data Guardian (NDG) for Health and Care's 'Review of Data Security, Consent and Opt-outs' report had considered risk stratification, which involved health professionals identifying individuals who may benefit from targeted interventions, but noted that some CCGs were using the same predictive tool for both risk stratification for case finding and risk stratification for planning. The NDG review considered that risk stratification for case finding, where carried out by a provider involved in the individual's care or by a data processor acting under contract with such a provider, should be treated as direct care for the purpose of the opt out, and therefore should not be subject to the opt out of personal confidential data being used for the purposes beyond direct care. NHS Digital noted that they were getting particular challenges with regard to commissioning, 'secondary use' and 'direct care', and IGARD noted that since the report was silent on whether commissioning should be treated as direct care that NHS Digital should seek the view of the NDG on this particular aspect. In addition, IGARD suggested that NHS Digital may wish to consider a number of real life commissioning examples where a question had arisen with regard to secondary use / direct care to test against the Caldicott Principals.
5	**AOB:** There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 25/10/19

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-15625-T8K6L -	Medicines and Healthcare Products Regulatory Agency (MHRA)	17/10/2019	1. To insert a new "Sub-licencing" section in the application to draw together all the statements (or to include additional information or refer to where supporting information can be found) to address all of the requirements of NHS Digital's Sub-licencing Standard.	IGARD Members	Quorum of IGARD Members	N/A

In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None