Resource report

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NHS Digital: Precedents Set

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Acknowledgements & Background

This project was funded as an Innovation award as part of the collaborative research programme entitled ‘Cohorts and Longitudinal Studies Enhancement Resources’ (CLOSER); ESRC grant reference: ES/K000357/1. CLOSER is a consortium including eight of the UKs major cohort and longitudinal studies. The CLOSER network brings these teams together to:

- stimulate interdisciplinary research across the major longitudinal studies
- provide shared resources for research
- assist with training and development for researchers in the use of longitudinal data at all career stages
- share information and expertise in longitudinal methodology.

This project – CLOSER work package 8 – aims to highlight means of linking longitudinal research studies to routine health records. The project draws on methodologies developed in the Project to Enhance ALSPAC through Record Linkage (PEARL) – a Wellcome Trust award (WT grant reference: WT086118/Z/08/Z) – that has developed linkages within the Avon Longitudinal Study of Parents and Children (ALSPAC). This particular report draws together evidence from across the whole UK longitudinal study community.

Much of the information presented within this report has been distilled from NHS Digital (and predecessor organizations) guidance documents. This includes our adaptations of some technical diagrams and graphics. The source documents have been acknowledged where appropriate.

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Contents

Summary

NHS Digital are 'data owners' for certain classes of English health information. They control and manage access to the NHS central population register and centralised secondary and community health care records. In addition they facilitate access to national registers. Access to NHS Digital controlled records has become a more rigorous process since a review of data sharing principles in 2014. This report aims to provide insights to help studies develop fit-for-purpose applications by signposting precedents set through approved applications from within the longitudinal study community.

Linkage to routine records is increasingly seen as an important data collection methodology within longitudinal research[1]. Researchers managing longitudinal population study (LPS) resources need to ensure that the linkage strategies they develop are acceptable to key stakeholders with particular emphasis on participant/public acceptability[2]. Managing this effectively requires an understanding of public expectations and addressing these in a transparent and effective manner without (overly) compromising scientific objectives. Failure to do this effectively – as evidenced by high-profile media stories portraying data use in a negative way - has led to public and political difficulties[3]. An example of this was the failed attempt by the Health and Social Care Information Centre to create a centralized primary care data repository through the care.data scheme. One direct result of the failure of care.data was a review of data sharing within the NHS Information Centre (a now defunct NHS unit which had responsibilities for sharing certain health and registry records for secondary use)[4] and subsequent organizational and procedural change instigated by NHS Digial. The period following this review has been characterized by studies struggling to negotiate new or continued access to NHS Digital (the NHS unit now responsible for sharing certain health and registry records) held data while NHS Digital revised their approach to data sharing and rolled out a new data sharing application process. More recently, some LPS have successfully negotiated permissions to extract and use NHS Digital owned records.

[1] Pell, J., 2014. Maximising the Value of UK Population Cohorts: MRC Strategic Review of the Largest UK Population Cohort Studies.
[2] Wellcome's Longitudinal Population Studies Working Group, 2017. Longitudinal Population Studies Strategy.
[3] Carter P, Laurie GT, Dixon-Woods M. The social license for research: why care.data ran into trouble. *J Med Ethics* 2015;**41**:404-9.
[4] Partridge, N. Review of data releases by the NHS Information Centre. 2014.

Aims & Disclaimer

NHS Digital do not have a formal 'precedents set' process or repository; however NHS Digital application managers refer back to past applications and there is an appetite to build new applications on the basis of successful past applications.

This document aims to help inform LPS managers' develop their NHS Digital applications through highlighting useful precedents set by past applications. I hope collating this information will be of use. Given the nature of this task, I consider this to be a 'living' document that will be updated to include new precedents or indication of changing views on issues. I welcome those submitting applications who have used this document to feedback information from their application process.

This document has not been endorsed by NHS Digital. Rather, it has been built around the public domain minutes resulting from LPS applications to access NHS Digital data. Data management and governance are both dynamic processes and there is no guarantee that approaches that were considered acceptable will be considered acceptable in the future. NHS Digital processes should be expected to evolve in light of changes such as the imminent Data Protection Act 2018 and the National Patient Data Opt-Out programme[5]. I strongly advise you contacting NHS Digital about your application as early in the process as possible[6].

CLOSER are actively working in partnership with NHS Digital to develop frameworks for data sharing with longitudinal studies. I hope, with my partners at CLOSER and NHS Digital, to provide more detail on these in the near future.

[5] https://digital.nhs.uk/national-data-opt-out
[6] https://digital.nhs.uk/data-and-information/data-services/data-access-request-service

UK Biobank application (2015)

UK Biobank Summary

On the 27/09/15 UK Biobanks application to share linked HSCIC data was granted conditional approval by the HSCIC Data Access Advisory Group (DAAG). The minutes of the application hearing are provided in Appendix 1.

The application sought approval for biobank to access HES records to use on a hypothesis free basis and to onwardly share with other researchers.

We note that this application is now relatively old, and the committee and NHS Digital application management thinking has changed in the meantime.

UK Biobank application features

- The committee required that where UK Biobank onwardly share data (i.e. to researchers), they impose equivalent controls to those used by HSCIC. The examples used to illustrate this point were:
- That UK Biobank need to compile a publicly available list of data users and uses;
- That UK Biobank ensure that all data uses were compliant with the Care Act 2014;
- That these [onward sharing] processes should be equivalent to those used by CPRD and CEGEDIM;
- That the data cannot be used for commercial purposes (although there seems to be some flexibility in the interpretation of this).
- That UK Biobank's consent wording is no longer seen as sufficient, but that it was in line with guidelines at the time of collection. While re-consent is not necessary, it is necessary to update information provided to participants.
- The committee repeatedly questioned participant withdrawal of consent mechanisms and how these wishes are implemented at a data management level.
- Applying for 'worldwide' data access raised multiple concerns. However, this was ultimately considered to be acceptable where: the data were de-identified (to the point where it could potentially be considered "anonymised in context"); a data sharing contract was entered into; participants were clearly informed their data would be used in this manner.

Recommendations based on UK Biobank application

- CLOSER applications clearly describe how they control for the issues raised by DAAG when considering the UK Biobank application.
- That materials provided to participants (e.g. via a study website), describe each data use and summarise the data used within that project. Studies could consider whether to provide an opt-out mechanism for any given project.
- That applications are clear and consistent when using the terms 'pseudonymised' and 'anonymised' (note the use of 'anonymised in context' by NHS Digital that relates to the Information Commissioner's Office Anonymisation Code of Practice).

National Child Development Study (2017)

NCDS Summary

On the 20/07/17 NCDS's application to link to NHS Digital data was granted conditional approval by the Independent Group Advising on the Release of Data (IGARD)[7]. The minutes of the application hearing are provided in Appendix 2.

The application sought approval to link the study to HES, but that the resulting linked data would only be used by UCL researchers (onward sharing was a stated objective of a future application).

NCDS application features

- That sharing beyond UCL was reserved to a future application.
- As the use of NHS ID had not been described in fair processing materials, the use of NHS ID in facilitating the linkage was blocked.

Recommendations based on NCDS application

- Fair processing materials need to contain 'technical' level detail describing data ownership and data transfer (using the term 'linkage' and the role of personal identifiers in this process).
- Fair processing materials need to describe that the study provides personal identifiers to the data owner for the purpose of linkage (and that means revealing participation in the study to the NHS).
- Applicants should discuss data retention holding periods with NHS Digital but be reassured that NHS Digital has acknowledged the need to hold data in order to account for scientific challenge and defense of published findings.

[7] http://content.digital.nhs.uk/media/24865/IGARD-Minutes-20-July-2017/pdf/IGARD_Minutes_20.07.17.pdf

Whitehall II application (2017)

Whitehall II Summary

On the 06/07/17 Whitehall II's application to link to NHS Digital data was granted conditional approval by the Independent Group Advising on the Release of Data (IGARD)[8].

The application sought (renewed) access to HES, Mental Health, ONS mortality and cancer registration and (new) access to the Diagnostic Imaging Dataset. The application used consent, 'Section 251' permissions and Approved Researcher as a legal basis for sharing identifiable data. The application did not seek approval for onward sharing of the data

Whitehall II application features

- The committee required that where Whitehall II onwardly share data (i.e. to researchers) that this happens within 'UCL approved projects' and it is not permissible to share to EU partners. It is not clear if this would permit UCL to share Whitehall II and linked NHS Digital data with researchers based at another UK institution.
- Fair processing requirements were highlighted as was the need for continuing 'fair processing' conversations with participants.
- The application is based on multiple legal bases, it is difficult to ensure a 'window' where all paper work is synchronized and not pending review.

Recommendations based Whitehall II application precedents

- That applications stress the longevity of the cohort, continuing participant engagement and the way in which the study provides news and fair processing updates.
- That materials provided to participants (e.g. via a study website), describe each data use and summarise the data used within that project.
- That applications are clear and consistent when describing the scope of onward sharing.

[8] http://content.digital.nhs.uk/media/24749/IGARD-Minutes-06-July-2017/pdf/IGARD_Minutes_06.07.17.pdf

ALSPAC application (2018)

ALSPAC Summary

On 11th January 2018 the ALSPAC application to link to HES data and MHSDS data was granted approval by the Independent Group Advising on the Release of Data (IGARD)[9].

This application gives a useful precedent for extracting data into the UKSeRP (MRC Farr CIPHER) secure research infrastructure. This infrastructure is being adopted by certain longitudinal studies (e.g. ALSPAC, UK Dementia Platform).

ALSPAC application features

- Long-term follow-up of participant exposure/outcomes using linked health records
- Use of UKSeRP as a secure host for data while being used by researchers from the University of Bristol.
- Use of both consent and s251 as a legal basis for linking and using records

Recommendations based on the ALSPAC application precedents

- That applications are written in clear English and are accessible to lay readers (as part of NHS Digital & IGARDS commitment to transparent data sharing)
- That NHS Digital application advisors prefer to 'split' consent and s251 applications into different, parallel, applications. This may have unforeseen consequences relating to account administration costs.
- That clear participant fair processing materials are used. These should be explicit about different legal basis used (now a GDPR/Data Protection Act 2018 requirement), and making clear the implications of non-response where s251 is used.
- Ensure clear description of UKSeRP in the application and full recognition that data will be transferred, stored and analysed at UKSeRP (i.e. University of Swansea are Data Processors under the Data Protection Act 1998).
- That the accompanying System Level Security Policy will need to fully describe all locations of data storage (i.e. in this case Bristol's primary data store, disaster recovery site, backup site, Swansea's primary data store, disaster recovery site, backup site).
- To ensure your institutions DPA registration[10] is clear and includes the purpose described in the application and also that the DPA registration of the infrastructure provider is also clear and appropriate.

[9] http://content.digital.nhs.uk/media/25070/IGARD-Minutes-10-August-2017/pdf/IGARD_Minutes_10.08.17.pdf

[10] You can search for organizational DPA registration details via this site: https://ico.org.uk/esdwebpages/search

Appendix 1: Minutes from the DAAG minutes relating to UK Biobank Application (2015)

28/04/2015
UK Biobank (Presenter: Garry Coleman) NIC-300295-L8Y9K Application: This application was presented to DAAG for advice only. In particular advice was requested on the consent model and materials used by UK Biobank, as it was noted that participant consent had been obtained some years previously and opinions regarding good practice for consent materials had progressed since then. Advice was also requested on the controls that should be in place for the onward sharing of data, given that UK Biobank would make the data provided by the HSCIC available to other researchers. Discussion: DAAG discussed the importance of ensuring that appropriate controls were in place for the onward disclosure of data. It was suggested that these should be comparable to the controls that were in place for HSCIC data disclosures, and for example UK Biobank should maintain and publish a register of data disclosures as well as ensuring that any uses of data were compliant with the Care Act 2014. DAAG agreed that these controls should be comparable to those in place for other organisations that shared HSCIC data onwards for use by third parties, such as CPRD and Cegedim. Confirmation was requested of how UK Biobank handled patient objections or the withdrawal of participant consent, as well as how these were handled by third party organisations accessing data. The consent materials were discussed and it was agreed that these would not be considered sufficient for any studies recruiting participants now, particularly as it was felt that the phrase ‘access to health data’ was not sufficiently clear. However it was acknowledged that recruitment had ended a number of years previously, and UK Biobank had consulted with appropriate bodies at the time when the consent materials were designed. DAAG agreed that the consent materials should be updated if any further participant recruitment was planned, but otherwise did not consider that this would be necessary. However, there were some concerns regarding the information made available to existing participants and DAAG emphasised the importance of ensuring that clearer information about how data was collected and used was made easily accessible to participants. Outcome: DAAG’s advice was that controls should be in place for the onward sharing of HSCIC supplied data that are comparable to those for other organisations such as CPRD and Cegedim. Clarification was requested of how the applicant addressed the requirements of the Care Act 2014, as well as how the applicant and its customers handled objections. DAAG advised that consent materials would only need to be updated if further recruitment was planned, but that clearer information should be made available to participants about how their data is collected and used.

09/06/2015
UK Biobank (Presenter: Garry Coleman) NIC-356143-V5D7L Application: This application had previously been brought to DAAG for advice on 28 April 2015. The applicant requested Hospital Episode Statistics (HES), Mental Health Minimum Dataset (MHMDS), Diagnostic Imaging Dataset (DIDs) and Personal Demographics Service (PDS) data for members of the UK Biobank cohort, who had previously consented to the use of their data. Following discussions at the 28 April 2015 DAAG meeting, additional information had been provided regarding controls around the onward sharing of data and how information was provided to cohort members. Discussion: DAAG queried whether recruitment of participants was still

underway. It was confirmed that recruitment of UK Biobank participants had ceased, but that existing participants could be contacted to ask whether they wished to participate in further assessments. The information made available to participants was discussed, and it was noted that while UK Biobank provided information on the projects that made use of UK Biobank data this did not seem to include details of what participant data was used for each project. DAAG advised that the applicant should consider publishing details at a more granular level of what participant data had been used for what particular projects, in addition to clarifying what data had been provided to UK Biobank by the HSCIC. DAAG queried how researchers using UK Biobank data would handle requests from participants for their data to no longer be used, if an individual chose to withdraw their consent. The potential Page 2 of 6 2.2 difficulty of removing an individual's data from a pseudonymised dataset after this had been provided to a researcher was noted, and it was suggested that the UK Biobank website should clearly state that requests for 'no further use' of data can only apply prospectively rather than retrospectively. A query was raised regarding a reference to researchers 'rendering data inaccessible' after a certain time period, and it was agreed that this wording would be amended to clarify that data would be destroyed. A reference to 'pseudo-anonymised' data was also queried, and it was confirmed that this should instead say pseudonymised. DAAG highlighted the need for UK Biobank to ensure that customers would not use the data for any commercial purpose, in order to comply with the requirement of the Care Act 2014 for the HSCIC to only share data for the purposes of health and social care or the promotion of health. It was agreed that a statement to this effect should be included in the application summary and the data sharing agreement. Outcome: Recommendation to approve subject to the applicant demonstrating compliance with the relevant requirements of the Care Act 2014 in terms of commercial uses. Advice was given that the applicant should review their fair processing materials published online and attempt to be as granular as possible in terms of how an individual's data is used.

18/08/2015
UK Biobank (Presenter: Steve Hudson) NIC-371826-W9C3Z Application: this application was considered by DAAG on the 9 June and recommended for approval with caveats. It was noted that the caveats had been addressed on the 13 July and a SIRO letter issued. The application is an amendment to a clerical error in the previous application which stated the 'UK' as the territory of use when it should have stated 'worldwide'. It was noted that this was the only amendment to the application. It was also noted that the IAO had concerns with regard to the patient safety leaflet and consent. Discussion: DAAG noted that the application submitted did not address if previous caveats had been met. DAAG asked that the correct version of applications be submitted to DAAG. DAAG noted that apart from the mention of 'worldwide' in the territory section of the application there was no additional information as the how the data would be shared worldwide, for what purpose it would be used, how long it would be held for, specific examples and data sharing security issues specific to individual countries, therefore DAAG could not adequately address the territory change or make an informed recommendation. DAAG asked for clarity around confusing terminology regarding anonymised and pseudonymised and that it could potentially be disclosive if shared worldwide. DAAG noted that the consent materials did not adequately address if patients had been informed that their data would be shared outside of the UK and that the applicants' website needed to be updated accordingly. DAAG also noted that the application was not explicit in excluding the use of data for commercial purposes and as per DAAG's previous

caveat. Outcome: The application was deferred. The application submitted did not reflect if the previous caveats raised by DAAG had been met. Clarification was also required around pseudonymised and anonymised data and that it could potentially be disclosive if data was shared worldwide, DAAG asked for clarity around how worldwide data sharing will work with specific examples and data sharing issues specific to certain countries. DAAG also noted the need to be explicit in Page 5 of 7 excluding the use of data for commercial purposes.

27/09/2015
UK Biobank (Presenter: Garry Coleman) NIC-371826-W9C3Z Application: This application, which requested an amendment to the territory of usage so that data could be shared worldwide, had been considered at the 18 August 2015 DAAG meeting when DAAG had deferred making a recommendation. Queries had been raised regarding how previous caveats had been met, the potential for commercial uses of data, clarification of sharing pseudonymised or anonymised data, and clarification regarding worldwide data sharing. Discussion: DAAG agreed that the point made at the 18 August 2015 meeting about reflecting the caveats previously made had now been addressed, although it was noted that some relevant sentences within the application summary had been deleted in error and these would be reinserted. DAAG discussed the second point previously made, regarding clarification around sharing anonymised or pseudonymised data. It was noted that the data would be treated as pseudonymised, although reasonable steps had been taken to de-identify the data and it could potentially be considered anonymised in context. The Material Transfer Agreement used by UK Biobank for worldwide data sharing included a strict prohibition on attempting to reidentify individuals within the data received. DAAG discussed the use of the Material Transfer Agreement, which stated that the agreement was governed by and in accordance with English law, and discussed the sanctions that could apply if an organisation breached its agreement with UK Biobank. DAAG agreed that this second point had also been addressed. The potential for data to be shared with commercial organisations was noted, but DAAG acknowledged UK Biobank's governance arrangements and noted that UK Biobank only accepted applications for data where the researcher would carry out health-related research that was in the public interest. It was agreed that the point DAAG had previously raised regarding potential commercial uses of data had therefore also been addressed. DAAG emphasised the importance of ensuring fair processing by making information about worldwide data sharing available to participants, and recommended that UK Biobank should publish some additional details about worldwide data sharing on the study website as soon as was reasonably possible. Given the potentially substantial benefits that could be achieved by sharing data worldwide, it was suggested that the HSCIC could work with UK Biobank over the coming months to produce a case study on the benefits of international data use. Outcome: Recommendation to approve. DAAG recommended the application for approval, noting the significant benefits being obtained from the work of UK Biobank, and DAAG welcomed the approach of Biobank to transparency including making all scientific papers available on their website. DAAG felt that this approach could be built on further, and would invite the HSCIC and UK Biobank by time of reapplication to develop a case study of benefits of international use of the data which could be made available on the HSCIC / UK Biobank websites as appropriate. This would help participants within UK Biobank appreciate further the international use of data. DAAG also recommended more immediately that strengthening the understanding around worldwide use of data (perhaps via a separate paragraph on the website detailing what data is being used where) would assist

with Fair Processing. Finally Page 5 of 10 2.8 2.9 DAAG asked that a specific sentence is included in the outputs section of the application summary such that international use is made explicit. Whilst these are not formal caveats to the approval, DAAG would expect that all have been addressed in a timely manner before a renewal application is considered.

Appendix 2: Minutes from the IGARD minutes relating to NCDS application (2017)

University College London - Centre for Longitudinal Studies Birth Cohort Studies Data Linkage: National Child Development Study (Presenter: Jen Donald) NIC-49297-Q7G1Q

Application:
This was a new application requesting the linkage of pseudonymised HES data to the 'Aged 50 Cohort' who had consented to the use of health data for research purposes. It was intended that a future amendment application would be submitted to request to make the linked research data available to other researchers, but the current application only requested the use of data by University College London. IGARD were informed that the study's fair processing materials had been reviewed against NHS Digital's nine criteria and had passed with the exception that University College London was not explicitly identified as a data controller.

Discussion:
IGARD discussed the identifiers that the applicant would provide into NHS Digital for linkage and noted a reference to NHS number, despite the fact that this did not seem to be covered by the participant consent. It was agreed the application should be amended to remove references to providing NHS number to NHS Digital. There was a discussion of whether the consent materials provided an appropriate legal basis for the planned linkage; on balance IGARD agreed that while the word 'linkage' was not explicitly used, this did seem to be implied by the description of using healthcare data. In addition it was acknowledged that participants had been actively involved in the study for a long time and it was considered that participants would not be surprised by the linkage of health data based on the information they had been provided with. IGARD discussed the fair processing information currently available to participants and in general noted their contentment but agreed that this would need to be updated to reflect University College London's role as data controller for this healthcare data. IGARD noted that the website already referred to making linked data available to other researchers in future, despite the fact that this had not yet been requested or agreed. It was agreed that the legal basis listed in section three of the application should be amended to refer to the correct subsection of the Health and Social Care Act 2012. There was a discussion of the indicative data retention period, as it was noted that application referred to retaining data until 2034 'in line with Department of Health guidance' but it was unclear what specific guidance this referred to. It was agreed the application should be updated to provide a clearer explanation of the reason for this. More widely it was agreed that NHS Digital should consider whether broad categories could be established to help agree what approximate length of data retention period would be appropriate for various uses of data.

Outcome:
Recommendation to approve, subject to: • The fair processing information published online should be updated to include a statement that University College London is the data controller. Page 7 of 18 2.7 2.8 The application should be updated to remove NHS number as a field that University College London would provide to NHS Digital, as this did not appear to be covered by participant consent. The legal

summary provided in the abstract section should be amended to clarify a reference to consent being in place for linkage. The legal basis under the Health and Social Care Act 2012 should be amended to refer to the relevant subsection. The reason for the indicative data retention period should be updated to provide a clearer explanation including explaining what guidance is referred to. It was agreed this condition would be considered out of committee by IGARD.

Action:
Garry Coleman to categorise different standard lengths of indicative data retention periods for general research and clinical trials, with appropriate justification.

Appendix 3: Minutes from the IGARD minutes relating to Whitehall II Application (2017)

University College London – Whitehall II (Presenter: Jen Donald) NIC-346693-F2X1G

Application:

This application was for the applicant to continue to receive HES, mental health data, ONS mortality data and cancer registration data for the Whitehall II study, as well as to additionally receive Diagnostic Imaging Dataset (DIDs) data. It was noted that this was a longrunning study of a specific cohort with section 251 support in place as well as Approved Researcher and Microdata Release Panel approval for the use of ONS data. IGARD were informed that any references in the application to sharing data with third party researchers Page 6 of 12 referred to the self-reported data, with the NHS Digital data only being used to verify the selfreported data. The applicant had committed to update the information for participants provided on their website and to provide updated information to participants as part of an upcoming survey.

Discussion:

IGARD discussed the applicant's commitment to provide updated fair processing information for participants, and agreed the importance of making these updates promptly. It was noted that the information sheet should more clearly explain the level of data that would be processed and what data would be shared with researchers. IGARD were informed that the study would issue updated information with the participant survey that would be sent out within the next few months, and it was noted that as the study continued to have a high response rate it was likely that the majority of participants would have sight of this updated information. It was agreed that the special condition wording in the application around fair processing updates should be amended to be clear that appropriate updates would need to be provided as part of the next wave of questionnaires. IGARD noted that the study's section 251 support seemed to have been due for renewal within the last few months and queried whether this renewal had been submitted and approved by HRA CAG. It was agreed this would need to be confirmed. A query was raised about the funding in place from European Commission Horizon 2020, and it was noted that the application referred to limitations on data sharing as part of the EUfunded LIFEPATH project. It was agreed the application should be amended to be clear that these limitations, which included not sharing record level data with funders or project partners and that the funders would not influence the outcomes of the study, would also apply to any other future EU funding or similar projects. In addition it was agreed that the application wording around 'making pseudonymised data available to the scientific community for use in UCL-approved research studies' should be amended to be clearer that this would not include sharing pseudonymised NHS Digital data with researchers such as partners to EU funded projects. IGARD discussed the way that NHS Digital data would be used to verify self-reported data, and queried whether the data shared with researchers would include any episodes from HES that an individual had self-reported. It was confirmed that if the self-reported data had not included an episode that was reported in HES, then that information would not be shared with researchers and therefore only things that had been self-reported would be shared. IGARD noted that the legal basis for dissemination listed in section five of the application currently only referred to section 261(7) of the Health and Social Care Act 2012 for some of the data, and that this should also refer

to the study's section 251 support. By this point of the meeting, not enough IGARD members were present to have a quorum; it was therefore agreed that a provisional recommendation should be given, with this to be ratified out of committee by the two IGARD members who had planned to be present for this agenda item but due to unforeseen circumstances had been unable to stay for the full agenda.

Outcome:

This provisional recommendation was made in committee and then was ratified out of committee by the IGARD Chair and one other IGARD member to reach a quorum. Recommendation to approve, subject to a condition: • Confirmation from HRA CAG of whether the study's section 251 support has been renewed. The application should be amended so that the special condition regarding patient information states that the applicant must appropriately update the information that will be provided to participants as part of the next wave questionnaires to refer to pseudonymised data rather than anonymous data. A reference in section five to "Making pseudonymised data available to the scientific community" should be amended to further explain this and to be clear this does not include Page 7 of 12 sharing NHS Digital data to researchers that are partners to EU funded projects. Section five should be updated to indicate that any future funding arrangements, including EU funding, will not include sharing NHS Digital record level data with these future funders or EU project participants, or permit them to influence the results or dissemination of results. The legal basis listed in section 3 should be updated to refer to the specific legal basis that enables dissemination as well as section 261(7) of the Health and Social Care Act 2012. It was agreed that the above condition would be reviewed out of committee by IGARD.

Appendix 4: Minutes from the IGARD minutes relating to ALSPAC Application (2017 & 2018)

15th February 2018

University of Bristol - MR1048b Continuation of Avon Longitudinal Study of Parents and Children (ALSPACT) with for the Children aspect only (Presenter: Duncan Easton) NIC152414-W3P6Q

Application: This was an application to renew and amend for a bespoke extract of Hospital Episode Statistics (HES) Admitted Patient Care, Critical Care, Outpatients and Accident & Emergency data as well as Mental Health Services Data and had been previously considered by IGARD on the 25 January 2018 when IGARD had deferred making a recommendation pending the application being redrafted to be more accessible to the reader; confirmation whether s251 general support covered projects 3 and 7; the retention period in the application cross referenced to HRA CAG approval; the legal basis for the retention of the original copy HES data to be stated; a clearer description of the filtering process; clearly describe the cohort; clearly state that University of Bristol will not link data requested unless permitted under this application; and the numbering convention to be clear throughout the application.

NHS Digital noted that a further three purposes had been included within the application for consideration and that further clarity had been given to the naming convention of supporting documentation.

Discussion: IGARD noted the application had been updated to reflect some of the comments previously raised, however IGARD noted the wording in Section 5a of the application was still not clear and suggested that it be updated in plain English in order to accessible to the lay reader. IGARD also noted that the cohort was still not clearly described, including the increase in cohort size and this should be cross referenced with the HRA CAG application summary and updated within section 5. IGARD were also still not clear of the filtering process outlined in section 5 and suggested that a clearer description of how the filtering process was conducted for transparency. IGARD noted it did not appear that the s251 general support provided by HRA CAG covered projects 9 and 10 as outlined in the application, agreeing that project 8 was covered by s251 general support, and that the applicant should identify the relevant s251 support for projects 9 and 10. IGARD queried if data under this application could be linked to other data and NHS Digital confirmed that it could not be linked and relevant wording was within section 5. IGARD suggested for transparency that standard wording within section 5 be updated from ‘the agreement’ to ‘the Data Sharing Agreement’ (DSA). IGARD queried the data retention period in section 8a and suggested that NHS Digital cross reference with the various s251 support letters submitted to ensure consistency, with appropriate standard wording including in section 5b.

IGARD noted that outputs would not be disseminated to patients, patient groups or the public and suggested that the applicant provide more information how the outputs would be made more accessible to the general public.

Outcome: recommended for approval subject to the following conditions:

• Confirmation which s.251 support documents cover the additional projects 9 and 10 listed within the application.
• To clearly describe the cohort in section 5 of the application.

The following amendments were requested:

• The application be updated to be more accessible to the reader.
• To provide a clearer description of the filtering process outlined in section 5 of the application.
• More information was requested about the planned outputs and how these will be made more accessible to patients.
• To update the planned data retention period section in line with the various s.251 support letters and update standard wording in section 5b.
• References in section 5b relating to "the agreement" should refer to "the DSA".

It was agreed that conditions be approved OOC by IGARD members

25th January 2018

University of Bristol – continuation of Avon Longtitudinal Study of Parents and Children (ALSPAC) with the children aspect only (Presenter: Duncan Easton) NIC-152414-W1M2Q Nicola Fear was an observer for this discussion.

Application: This was an application to renew and amend for bespoke extracts of Hospital Episode Statistics (HES) Admitted Patient Care, Critical Care, Outpatient and Accident & Emergency data as well as Mental Health Services Data. ALSPAC is a transgenerational prospective birth cohort study that recruited women during pregnancy during the 1990's. ALSPAC is designed to investigate influences on health, wellbeing and development across the life course. The seven purposes for the use of data requested cover various factors of mental and physiological health, including the connection between drug use and mental health outcomes, various aspects of self harm and sexual health. Duncan Easton noted that a previous linked application, NIC-13133 University of Bristol had previously been considered by IGARD on the 21 December 2017.

Discussion: IGARD were unclear what the application was requesting noting the wording in Section 5 of the application was ambiguous and suggested that it be updated in plain English to be clear to the reader, including ensuring that for each project a numbering convention be applied and used consistently across the application, particularly in regard to the table of supporting documents. IGARD noted it was not clear whether the s251 general approval provided by HRA CAG covered projects 3 and 7 as outlined in the application. Although IGARD noted that this application was the second of two applications to IGARD, it was suggested that further detail be added to Section 5 of the application to more accurately reflect the legal basis for each project. IGARD were not clear of the filtering processing outlined in Section 5 and suggested that a clearer description be given for transparency.

IGARD queried the applicant's retention of the full HES data set and it was noted that a full refresh had been requested due to the increase in the cohort size. IGARD noted that the legal basis to retain the HES dataset may have been outlined in the previous application (NIC 13133) however the legal basis for the retention of the original copy of the HES data should be clearly stated and cross referenced in this application summary for transparency. IGARD queried if data would be linked to any other data and that it be explicit in Section 5 of the application that data will not be linked and there should be no attempt to reidentify the previous extract for consenting index children. IGARD noted that the cohort should also be more clearly described in Section 5 of the application, including the increase in the cohort size. IGARD suggested that the retention period agreed for each project by HRA CAG be cross referenced with Section 8a of the application.

Outcome: recommendation deferred, pending:
• The application be updated to be more accessible to the reader.
• Confirmation whether the s.251 general approval provided by HRA CAG covers projects 3 and 7 listed within the application, and that the retention period agreed for each project by HRA CAG are cross referenced to section 8a of the application.
• The legal basis for the retention of the original copy HES data be clearly stated within the application summary.
• To provide a clearer description of the filtering process outlined in section 5 of the application.
• To clearly describe the cohort in section 5 of the application.
• Section five of the application should be updated to more clearly state that University of Bristol will not link data requested in this application to any other data, apart from the linkages permitted under this application, and that there should be no attempt to reidentify previous extract for consenting index children.
• The numbering convention for each project be applied across the entire application.

11th January 2018

University of Bristol – continuation of Avon Longitudinal Study of Parents and Children (ALSPAC) for the children aspect only (Presenter: Duncan Easton) NIC-13133-B7B3K

Application: This application for bespoke extracts of Hospital Episode Statistics Admitted Patient Care, Critical Care, Outpatient and Accident and Emergency data as well as Office for National Statistics Cancer registration and death data had previously been considered by IGARD on the 21st December 2017 when IGARD had deferred making a recommendation pending the applicant providing a copy of all previous versions of consent materials from when the cohort consented at age 16; and that the application be redrafted to more accurately reflect the cohorts, the processing activities and the projects that are covered by the consent as the legal basis.

Discussion: IGARD noted the application had been updated to reflect comments previously raised. IGARD noted that a reference to 'previous data extracts' within section 5a of the application referred to a processing activity and should be moved to section 5b.

IGARD queried two supporting documents that were both named 'Supporting Document (SD) 8' and suggested that one should be renamed accordingly. IGARD noted that consent versions 7 and 7.1 provided with the application notified cohort participants that if they did not respond to consent notices then they would not be exercising their right not to be included, because of the section 251 support. IGARD welcomed this as an exemplar for best practice.

IGARD noted that the applicant's DSA with NHS Digital had expired and that NHS Digital should progress as per due process.

Outcome: Recommendation to approve

The following amendments were requested:
• Reference describing processing activity within Section 5a to be moved to Section 5b of the application
• One of the two supporting documents referenced as 'SD8' to be renamed accordingly.
IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired, and that NHS Digital should progress as per due process.

21st December 2017

University of Bristol – (Presenter: Jen Donald) NIC-13133-B7B3K
Nicola Fear was not present for the discussion of this application due to a conflict of interests.

Application: This was an application to renew and amend two existing Data Sharing Agreements (DSA) for bespoke extracts of Hospital Episode Statistics (HES) Admitted Patient Care (APC), Critical Care (CC), Outpatient (OP) and Accident & Emergency (A&E) data as well as Office for National Statistics (ONS) Cancer registration and death data. ALSPAC is a transgenerational prospective birth cohort study that recruited women during pregnancy in the early 1990's and is designed to investigate influences on health, wellbeing, epigenetic, biological, psychological, social and environmental exposures and a similar range of health, social and development outcomes.

Discussion: IGARD queried the consent material received and noted that earlier versions of the consent forms from when the cohort reached the age of 16 in 2004 should be provided. NHS Digital confirmed that only the children from the original cohort had been re-consented however it was noted that the legal basis for the dissemination of data was not clear and asked for clarification as to why S251 detail was included. It was suggested that NHS Digital redraft the application to remove reference to S251 projects and cohorts and that section 5 be updated to more accurately reflect the projects undertaken, confirm the legal basis for the cohort which are currently confirmed by consent and that the processing activities be updated.

IGARD suggested that applicant update their DPA registration to more clearly state that data is processed about patients or healthcare users.

Outcome: Recommendation deferred, pending

☐ The application should be redrafted to more accurately reflect the cohorts, the processing activities and the projects that are covered by consent, as the legal basis.

☐ The applicant to provide a copy of all previous earlier consent materials from when the cohort consented at age of 16