THE RAINE STUDY

The Western Australian Pregnancy Cohort (Raine) Study

DATA & BIOLOGICAL SAMPLES ACCESS POLICY

Interim Update April 2016
Version 3.3

The Raine Study Executive Committee
Supported by

Overview

The Western Australian Pregnancy Cohort (Raine) Study

In 1989 a group of prominent Western Australian investigators (Professors Newnham, Stanley, Landau and Michael) had the foresight to establish a cohort of children to determine how events during pregnancy and childhood influence health in later life. From the original 2900 pregnancies, a cohort of 2868 children, the Western Australian Pregnancy Cohort (Raine) Study, has been followed closely over the last 25 years.

The Raine Study has been conducted by a collaborative team of researchers from:

- The University of Western Australia
- The Telethon Kids Institute
- The Lions Eye Institute
- The Women and Infants Research Foundation
- The Ear Science Institute
- Curtin University
- The University of Notre Dame
- Edith Cowan University

Since the inception of the Raine Study in 1989, more than $29M has been invested in the Raine Study. This funding has been received from 65 grant applications from over 15 funding bodies. The largest sums of funding for the Raine Study have come from the NH&MRC with other sources of funding including the ARC, Raine Foundation, Healthway, Canadian Institutes for Health Research, Asthma Foundation, Telstra Foundation, Australian Arthritis Foundation, Ada Bartholomew Medical Research Trust and Rotary Health.

The Raine Study is one of the largest successful prospective cohorts of pregnancy, childhood and adolescence to be carried out anywhere in the world. The Raine cohort is well established and there is frequent contact between enrolled families and study organizers. Retention rates are high and there is enthusiasm amongst participants to provide high quality information.

The Raine Study is an invaluable asset to Western Australian researchers. Currently more than 140 researchers utilise the resource and as the cohort grows older, its value will continue to increase. Currently there are more than 70,000 phenotypic variables available on each member of the cohort. Moreover, there are over 20 million genetic variants available on the majority of the cohort. There are committed teams of investigators utilising the Raine Study covering 25 broad areas of research. There is collaborative research between Raine Study Principal Investigators. Further, national and international collaborations with the Raine Study are continuing to develop and add value to the cohort and expand research opportunities. The Raine Study is an invaluable resource for future young investigators and graduate students and to the contribution of new knowledge for the public benefit.

Definitions

For the purposes of this policy:

1. "Executive" refers to the Raine Study Executive Committee. The Executive is responsible for overseeing the management of the Raine Study and for administering this Access Policy.
2. "Raine Secretariat" refers to the core leadership team (Scientific Director (s), Study Manager, Data Manager). The Raine Secretariat responsibilities include:
    a. Maintenance of the Raine Study cohort
    b. Strategic and operational management of Raine Study cohort
    c. Processing and coordinating all requests for existing data
    d. To oversee and co-ordinate Raine Research groups
    e. Maximize utilization / output / value / opportunities for the Raine Study
3. "Data" includes all information (in an anonymised form) available for access by approved researchers, relating to the participants' health, lifestyle, environment, biological samples, genetic data and data derived from sample analyses.
4. "Policy" refers to this Data Access Policy.
5. "Custodians" or "Owners" of all the Raine Study Data is the Executive.
6. "Principal Investigators" are senior researchers who have contributed to the funding and collection of specific data.
7. "Stewards" of data sets are principal investigators who have funded specific data collections e.g. Trier social stress test, liver ultrasound measures, male fertility, genetic information.
8. "Raine Study Research Groups" are established groups of investigators who work collaboratively together and whose status as a "Raine Study Research Group" has been recognised by the Executive.
9. "Researcher(s)" refers to the user, or group of users, of the data requested.
10. "Analytical Dataset" refers to de-identified Raine Study cohort data available to approved researchers.
11. "Raine Study Team" refers to the core group of long term cohort review staff with substantive experience in cohort reviews and a long history of contact with the cohort.

The Raine Study Resource

The Executive will encourage and provide access to the Raine Study Resource and the resulting information as widely and as openly as possible in order to maximise the value of the resource.

The Executive will act as custodians of all data and biological samples.

Data location

All phenotype data sets are on stored secure servers at the University of Western Australia.

All genotype data are stored on the iVEC supercomputer, a joint venture of UWA, Curtin University, CSIRO, Edith Cowan University and Murdoch University. This secure resource is supported by the Western Australian Government and the Federal Government.

The biological samples are currently stored at the Telethon Kids Institute, King Edward Memorial Hospital, Royal Perth Hospital and the Western Australian DNA Bank at Sir Charles Gairdner Hospital and the Raine Study Offices at UWA.

Scope of this Policy

The scope of this policy covers all requests for access to Data from the Raine Study and for access to collect information from the cohort, regardless of who makes the request.

Please note that any linkages of health information to the Raine Study Data must be applied for in accordance to the contents of this policy as well as the protocols of the Data Linkage Unit (DLU) (http://www.datalinkage-wa.org/)

This policy will be effective from the 1st September 2014 and will be applied to all current and future applications.

This policy will be updated as required and the latest versions of the relevant documents will be available on the Raine Study Website (www.rainestudy.org.au). It is the responsibility of the researchers and analysts to be aware of and adhere to any changes.

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1. PRINCIPLES OF ACCESS

1.1 General

- The Raine Study data will be managed in order to optimise its utilisation and value for research and public benefit.
- Access to the Raine Study data and biological samples is through the process detailed in this policy.
- All applications to collect or utilise data are considered and require prior approval by the Executive.
- Access to Data should be achieved through collaboration with a member of an existing Raine Study Research Group.
- The Raine Study Secretariat will assist in linking new investigators with existing researchers working on related topics.
- Researchers are required to provide evidence that their research proposal has appropriate ethics approval. In some instances researchers will be required to obtain additional approval from an appropriate Human Research Ethics Committee (HREC). All HREC applications are to be reviewed by the Raine Secretariat prior to submission to the HREC and a copy of all HREC applications, approvals and extensions must be provided to the Raine Secretariat.
- The Chief Investigator nominated in the Access Application will ensure that all Committees (HREC, Executive) are notified of any change in personnel, protocol or physical location of the research data or any derivatives.
- The Chief Investigator must ensure that all research staff with access to Raine data are made aware of their responsibilities and have signed the Raine Study *Data Access Agreement* (Appendix A). Chief Investigators must immediately notify the Executive of any change in the list of researchers utilising Raine data.

2. ACCESS TO DATA AND PARTICIPANTS

2.1 Access to Previously Collected Data

Access to Data is only permitted by application. The process for application to use Raine Study data will be fair, standardised and transparent. Access to Data will only be permitted for research that is consistent with the principles of the Raine Study. All access to Data requires appropriate ethics approval and consent of the participants.

2.2 De-identification of Data

All information that identifies participants will be removed from the Data before they are released to researchers.

Researchers may have encrypted identifiers, unique to their research group, included with their datasets. The encrypted identifiers are linked to the investigator (research group) making the data request such that investigators can merge subsequent data extracts utilising their unique identifier.

Researchers at not permitted to merge their Raine data extracts with data that have been provided to other Raine Study Research groups. The encrypted identifiers are unique to each research group.

2.3 Criteria for Prioritisation of Access

Investigators who have funded **specific data collection** (e.g. genetic and epigenetic datasets, back pain, liver ultrasound or Trier Social Stress Test datasets) during Raine Study cohort reviews are identified as 'stewards' of those specific datasets. The Executive is the owner and custodian of all data and biological samples.

Investigators who have funded specific data collection will have priority of access to these data for a period of two years from the time when these data become available.

Stewards of specific datasets will be consulted when permission is sought to access these data for at least four years after these data have become available.

2.4 Access to biological samples

The Raine Study has stored biological samples that were collected from the mother during pregnancy (16-18 weeks and 34 weeks gestation) and the child at delivery, five, fourteen, seventeen , twenty and twenty two years of age. Biological samples collected from the parents of the participants have been stored.

Blood and urine samples are stored at -80 degrees and detailed records are kept relating to aliquot volumes and freeze thaw cycles.

Biological samples from the Raine Study are a finite resource and utilisation of these samples needs to afford the maximum benefit to Raine Study researchers and the wider research community.

Although biological samples have been collected and processed by a number of Principal Investigators, the Executive have ownership and custodianship of all biological samples collected from the Raine Study participants and their families.

The overriding principle associated with the collection of biological samples is that they are collected for the benefit of all investigators and the Raine Study.

Where deemed appropriate by the Executive or Secretariat, Principal Investigators who have collected specific biological samples will be consulted by the Raine Secretariat when requests are made to access the particular biological samples.

Requests to access the Raine Study Biological samples require the completion of an Access to biological samples form (B form, Appendix F) and approval obtained from the Executive. Completed B forms must be submitted to the Raine Study secretariat at least two weeks prior to an Executive meeting.

Each request to access biological samples will be considered as to the:

- Strategic importance of the proposed analyses
- Benefit to the wider Raine Study investigators
- Feasibility of performing other analyses at the same time to maximise the value of the finite resources

Researchers are required to provide the following information to the Executive with all applications to access biological samples:

- Which biological sample will be utilised
- Volume of sample required for analyses
- Do freeze/thaws influence sample analyses

  [Freeze/thaws may influence subsequent unknown tests]
- Where will sample analyses be performed and justification for the utilisation of the facility
- Evidence of validation of the analytic platform selected
- Evidence that the specific analyte(s) is measurable in the proposed biological sample
- What quality control exists for sample analyses (e.g. duplicates, triplicates)
- Information on sample transportation to the testing facility and for the return of any samples remaining after the analyses are complete
- Evidence of value of the data to the Raine research community and the broader research community

Prior to receipt of the biological sample, researchers must complete a *Materials Transfer Agreement (MTA)* (Appendix G) and return the signed document to the Raine Secretariat.

Researchers wishing to utilise biological samples are required to return the derived variables from these samples to the Raine Secretariat. These data will be made available to the Raine Study research community utilising the principles outlined in this policy.

2.4.1 Physical release of samples

The Executive will only approve physical release of samples to researchers who have completed the application process justifying the use of the biological samples.

Laboratories performing analyses on Raine biological samples are required to sign the Raine Study *Data Access Agreement* as well as the Raine Study *MTA*.

Samples may only be used for the agreed purposes and in accordance with the consent of Raine Study participants.

Any biological sample that remains after analyses are complete is to be returned to the Raine Secretariat.

All costs incurred in sample preparation, shipment (including return of residual samples) and analyses are borne by the Principal Investigator proposing to utilise the biological sample.

2.5 Access to genetic and epigenetic data

Genetic and epigenetic data, both genotyped and imputed, on members of the Raine cohort (and their parents) are owned by the Executive. All applications to utilise genetic and epigenetic data requires prior approval from the Executive.

In line with NH&MRC guidelines, all applications to utilise genetic and epigenetic data from the Raine Study will require appropriate HREC approval and appropriate participant consent.

Research groups who request to utilise the genetic and epigenetic data are encouraged to collaborate with at least one member of the Principal Investigator Team who obtained grant funding for the genetic and epigenetic data. Researchers who wish to utilise Raine Study genetic or epigenetic data without collaboration with at least one of these Principal Investigators are required to justify this in their application to utilise the genetic data.

Applications to use phenotypic data from specific datasets (e.g. back pain, liver ultrasound or Trier Social Stress Test datasets) in the Raine Study for genetic or epigenetic association studies will usually require discussion with the Principal Investigator who funded the collection of the specific dataset. This is co-ordinated via the Raine Study Secretariat.

As a general principle, no linked phenotype-genotypic or phenotype-epigenetic data will be transferred outside of Perth for the purpose of original research; however, limited amounts of data may be permitted to be analysed outside of Perth for the purpose of replication studies and when Raine genetic or epigenetic data are being utilised as control samples.

All Raine Study genetic and epigenetic data are stored on iVEC. Analysis of Raine Study Genetic data is run on iVEC.*****

Resources are available within the Raine Study investigators to assist new investigators to analyse genetic data.

All original genome-wide genotype and epigenetic data will undergo quality control (QC) by a Raine-approved core analyst to ensure uniformity, accuracy and validity of the data

prior to use in disease-specific association studies. All QC procedures will be documented on iVEC.

De-identified genotypic and epigenetic data from the genome-wide analyses will be made available as control data for investigators analysing specific phenotypes outside of the Raine cohort through collaboration with one or more of the Principal Investigators who funded the original genotyping providing that involvement in the collaboration is scientifically and ethically sound and that the Raine cohort is protected and appropriately acknowledged.

Prior to submission for approval from the Executive, applications to use the Raine Study genetic data will be forwarded to the Raine Study Genetics Advisory Subcommittee. This Subcommittee will advise the Executive on all applications to utilise the Raine Study genetic data. The responsibilities of this advisory subcommittee include ensuring that:

- relevant investigators have been consulted in relation to the proposed study
- relevant investigators are included in the proposed study
- the scientific validity of the proposed study is not in question
- the proposed project does not overlap with other projects in progress
- the analyses will be performed in an appropriate location
- the analyses will be performed by adequately experienced researchers
- the analytic support required for the project is appropriate
- that appropriate computer resources will be utilised
- that mirrored analysis will be performed in a suitable location by suitably experience researchers
- that quality control processes have been established for data analysis
- that all involved investigators have read and signed the Raine Study *Data Access Agreement*.

iVEC is an unincorporated joint venture of CSIRO and the four public WA universities with funding from the State Government. iVEC fosters and promotes scientific and technological innovation through the provision of supercomputing and eResearch services to the research community, commercial organisations and government agencies. In 2009, iVEC was charged with establishing and operating the $80 million Pawsey Centre by the Australian government. (www.ivec.org)

The Raine genetic data are stored in iVEC. Only authorised users are given access to the Raine Study genotype data. Only Raine Study nominated representative can create user accounts for new researchers.

2.6 Access to the cohort

Contact between cohort participants and Raine Study investigators require prior knowledge and approval from the Executive.

Liaison with members of the cohort is managed and directed through the Raine Study Secretariat.

No investigators should contact Raine Study participants or families without the knowledge and approval of the Raine Secretariat. Only members of the Raine Study Review Team or collaborators working directly in collaboration with the Review Team will be allowed to contact study participants.

2.7 Collection of new data

Formal cohort reviews occur every two to three years. These reviews are coordinated by the Raine Secretariat and are designed to generally be contained within a four hour period to limit cohort burden.

Applications to collect data during cohort reviews are coordinated by the Raine Secretariat.

Formal applications to collect new data on the cohort are reviewed and approved by the Executive.

On some occasions, cohort contact may occur outside of the formal Raine cohort reviews that occur every two to three years, especially if this involves a subset of the cohort or online questionnaires. All applications to contact the cohort outside of formal cohort reviews will be considered individually on their merits by the Executive.

As a general principle, cohort review and data collection from the cohort will be co-ordinated and conducted by the Raine Study Review Team.

In conjunction with the Raine Study Review Team, specialised research assistants or clinicians may be required for specific assessment protocols.

2.8 Access by new Research Groups

As a general principle, all researchers or research groups who wish to utilise Raine data require collaboration with an established Raine Study Research Group.

Local Raine Study collaborators must ensure that if data is located outside of Western Australia, the locations of all copies of Data are specified fully in the *Data Access Agreement*. Further, local Raine Study collaborators must ensure that appropriate data security is met for each location.

2.9 National and International Collaboration

All research collaborations involving researchers not previously associated with the Raine Study require approval of the Executive via the completion of a collaboration form, (C form, Appendix C).

Research groups where the Principal Investigator is located outside of WA, require a Western Australian Raine Study Investigator to be a nominated project coordinator.

All projects are required to provide the Raine Secretariat with the nominated project coordinator. Project coordinators are nominally responsible for research activities undertaken by the Study Group.

3. TERMS OF ACCESS

3.1 Access Agreement

Every researcher accessing Data will be required to enter into *Data Access Agreement* (Appendix A). This will specify the Principal Researcher and all researchers utilising the Data and the specific purpose for which the Data are to be used.

The *Data Access Agreement* will specify that the project must be completed within an agreed time frame. Any application to extend the *Data Access Agreement* must be made to the Raine Secretariat at least 30 days prior to the agreed project completion date.

All Researchers must agree not to attempt to make unauthorised mergers with other Raine Data extracts, including Data files provided for separately approved projects.

All Researchers must agree not to provide Data to other researchers outside of approved projects.

All Researchers must agree not to use the Data files for any purpose other than to achieve the research objectives specified in the approved project.

The Recipient must notify the Raine Secretariat of any errors found within the dataset for core database maintenance.

Any new data derived from samples or study subjects shall be lodged back with the Raine Secretariat at the completion of the project.

The Researcher must agree to delete all Raine Data files at the completion of their approved project.

If Raine Study data files are required to be stored in accordance with publication specifications, they must be appropriately archived on a secure server.

3.2 Fees

The Raine Study has a fee structure for data access and cohort access. This has been set at a level to not discourage use of the resource.

3.2.1 15% Fee on Grant applications

When research grant applications are made to analyse existing data or to collect new data, a 15% cohort access fee will be charged. This fee is to be included in the grant application. Guidelines for justification of the access fee are available from the Raine Secretariat.

- The cohort access fee is capped at $65,000
- Grants under $20,000 are exempt from the cohort access fee
- No access fees are levied on awards and scholarship applications.

For Investigators/students associated with existing Raine Research Groups, the access fee is not charged where funding is sought for

- Fellowship Awards (Including Research, Practitioner, Career Development and Australia Fellowships)
- Training (Postdoctoral) awards
- Scholarships

3.2.2 Access fees for existing data provided to Raine Study Principal Investigators

Established Raine Study Principal Investigators (and their students including Masters, Bachelor of Medical Science, PhD and Post Doctoral Research Fellows) who have contributed to data collection and are employed by institutions that provide funds for Raine Study Core Management (currently UWA, Telethon Kids Institute, WIRF, Raine Medical Research Foundation, Curtin University, Edith Cowan University) are exempt from fees associated with access to Raine Study data provided their data requests are reasonable and they do not place an unreasonable burden on the Raine Study Data Manager.

Raine Study Principal Investigators (and their students including Honours, Masters, Bachelor of Medical Science, PhD and Post Doctoral Research Fellows) who are employed by institutions that do not provide funds for Raine Study Core Management will be charged a data access fee on a sliding scale from $2,500 to $5,000 dependent on the size of the data request.

Additional data requests for approved projects will be charged if the cumulative data requests exceed a total to 5 hours of data management, at a rate of $200/hr.

Access fees are charged on a project by project basis. Projects are defined through the projects approval process.

3.2.3 Access fees associated with access to existing data for New Investigators

New investigators who are employed by institutions that do not provide funds for Raine Study Core management will be charged the same data access fees as Raine Study Principal Investigators who are employed by institutions that do not provide funds for Raine Study Core Management.

New investigators who work at non-contributing Institutions and who are the lead researcher or lead author on the project, and who work in collaboration with existing Raine Study investigators who are employed by institutions that provide funds for Raine Study Core Management will be charged the data access fees.

3.2.4 Collection of New Data

Investigators will be expected to meet costs of collection of new data. Investigators are encouraged to apply for funding for data collection two years in advance of the proposed start date for data collection to secure a commitment to include these data.

Funding obtained for contacting the cohort, recruitment, data collection and the conduct of the proposed cohort review will be transferred to the Raine Secretariat to enable pooling of resources to contribute to the funding of the Raine Study Review Team.

Cohort review and data collection from the cohort participants are co-ordinated and conducted by the Raine Study Review Team

3.2.5 Reports for Outside Agencies

A data access fee of 30% of the total cost of generating the report will be levied by the Raine Secretariat. The data access fees are directed towards future costs incurred in Raine Study Core Management.

3.2.6 Data for Commercial use

Any request for Raine Study data or resources for commercial use will be considered by the Raine Study Secretariat and reviewed and potentially approved by the Executive Committee. Management of the request and the data access fee will be negotiated and charged at a commercial rate.

3.3 Security Measures

Researchers who are granted access to Data must ensure that adequate security measures are taken to safeguard the data. The Recipient must treat as confidential information any data or other information provided must take all reasonable and necessary precautions to restrict access to researchers who are directly involved in the approved project.

3.4 Intellectual Property and Royalties

As a general principle, IP is owned by the employee's employer. An employee therefore cannot claim IP ownership, or assign ownership to a third party.

Researchers are 'employees' of different institutions. Researchers are grant holders of grants administered from various institutions.

These institutions will have policies and relevant procedures which determine the ownership and/or assignment, if any, of Intellectual Property (IP) rights.

These Institutions will have policies, and relevant procedures, that require employees, or grant holders to acknowledge the relevant ownership and rights associated with IP.

Where there is more than one institution involved, the proportioning of ownership of any IP resulting from the use of the Raine Study Cohort, the Raine Study database or biological samples needs to ideally be decided at the commencement of the project, or at the time when the existence of IP is identified.

The Executive will advise on any apportionment of IP resulting from access to the Raine Study Cohort, the Raine Study Database and Biological samples. As a general principle, The Executive will determine the use of IP on behalf of the owners.

4. APPLICATION PROCESS

All applications to access the Raine Study Data should be submitted to the Raine Secretariat. Applications are collated and tabled at the Executive meetings.

All projects, collaborations and access to biological samples require approval from the Executive before the project can commence.

Executive approval is the first step in the process to access the Raine Study Resource.

Human Research Ethics Approval needs to be in place before access to Raine Study resources is granted.

All other relevant documentation is required to be finalised before access the cohort or the cohort resources may occur, e.g. multi-institutional agreements, memorandum of understanding between collaborators, material transfer agreements, data access agreement.

4.1 Application process

4.1.1 Project proposal

All new research proposals require a completed project proposal application form (P form, Appendix B) to be submitted to the Raine Secretariat in the first instance. This process will allow the Secretariat to assess the viability of the project and the availability of existing data to fulfil the project objectives. The P-form also allows the Secretariat to identify any potential overlap with currently approved projects.

All project proposals must include an established Raine Study Investigator.

All project proposals require approval from the Executive before they commence. P forms will be forwarded to the Executive for review at the Executive meeting. All project forms must be forwarded at least two weeks before the date of the Executive meeting to be included in the meeting agenda.

4.1.2 Grant proposals

All research grant proposals utilising Raine Study data or to collect new data on the Raine cohort require a project proposal application (P form) to be submitted to the Secretariat for review by the Executive.

All proposals require approval by the Executive prior to submission of the research grant. The Secretariat can facilitate a virtual Executive meeting for grant applications with short lead times.

4.1.3 Student projects (PhD, Master, Honours, BMedSci, other)

All students wishing to utilise the Raine Study for their research project must have at least one supervisor who is an established Raine Study Investigator.

All students (PhD, Masters, Honours, BMedSci) utilising the Raine Study must seek project approval through the Raine Study approval processes.

All PhD students must complete a project application form (P-form) (Appendix B).

Where masters, honours or other student projects form part of a previously approved project, the student can complete a P amendment form (Appendix D), referencing the approved P form, and providing details of their project and supervisors.

Where the student joins an established collaborative research group, the student can complete a C amendment form (Appendix E), referencing the approved collaboration form (C form).

All students are expected to publish their research findings.

All students must complete and sign the Raine Study Data Access Agreement (Appendix A).

4.1.4 Collaborations

Researchers are encouraged to collaborate with other expert researchers, locally, nationally and internationally. New collaborations require approval from the Executive. Researchers must complete an approval for collaboration form (C form, Appendix C) and forward this to the Secretariat.

4.1.5 Amendments to approved projects and collaborations.

Where amendments are made to existing projects, (e.gs where a research grant is resubmitted or the project is amended) researchers must complete a P amendment form (Appendix D).

Where a new collaborator already associated with an existing project group (e.g from the same institution or research group) joins an approved project, researchers must complete a C amendment form, (Appendix E) and the new collaborator must complete and sign a Data Access Agreement (Appendix A).

4.2 Linkage with other datasets.

Proposals to link Raine data with other datasets require Executive approval. A project proposal (P form) should be completed and submitted to the Secretariat.

4.3 Human Research Ethics Application

All ethics applications to appropriate institutional Human Research Ethics Committees must be made in collaboration with the Secretariat.

All HREC applications are to be reviewed by the Raine Secretariat prior to submission to the HREC and a copy of all applications will be kept on file by the Raine Secretariat.

4.4 Confidentiality

All research and IT staff who have access to the Data must be named in the project proposal.

4.5 Access Agreement

Once the application process to utilise Raine data is complete, any Researcher who will access the data will need to sign a *Data Access Agreement* (Appendix A) to ensure conditions for access are agreed upon.

A copy of the *Data Access Agreement* is kept by both the investigator and the Secretariat.

5. DISSEMINATION OF RESEARCH RESULTS

Researchers will disseminate results of their research as widely as possible.

5.1 Manuscript proposals

Researchers are requested to complete a manuscript proposal form (M1 form, Appendix H) outlining proposed publications for the Raine Secretariat for review.

The Raine Secretariat will review the M1 form for feasibility, availability of data and authorship. This ensures that there is no overlap with other papers that are currently in preparation or under review. Approval for the manuscript proposal and data access will be sent to the researcher.

Once an M1 form is approved, researchers have **two years** to complete the manuscript and submit it for publication. If the manuscript is not submitted within two years, the data and the manuscript proposal return to the Secretariat and other investigators are free to apply to utilise the data to prepare a manuscript.

Applications for extension of the **two years** will be considered by the Secretariat.

M1 forms that are currently active are available for review on the Raine Study website (*www.rainestudy.org.au*).

5.2 Submission for publication

All manuscripts are to be sent to the Raine Secretariat prior to submission for publication with a completed M2 form (Appendix I). Papers will be reviewed to confirm internal consistency or reporting (e.g. sample size, years of cohort review), publication quality and appropriate acknowledgments.

If a manuscript requires substantial author corrections, or the authors substantially modify the content in order to submit to a different journal, this manuscript approval process needs to be repeated for the modified manuscript.

The manuscript review process will generally take 7-14 days to complete.

5.2.1 Acknowledgements

There is an agreed standard acknowledgements section to be included in all manuscripts and publications (Appendix K). The relevant acknowledgements should be included as is or can be modified if there are specific journal requirements.

5.2.2 Media coverage

Researchers are to liaise with the Raine Secretariat over all media coverage. All media releases must be sent to the Raine Study Secretariat prior to release (M3 form, Appendix J).

The general Raine Study policy is that there is a media embargo on results until the paper is published.

Some journals have very strict media policies. Publicity can jeopardise the publication of papers, if this contravenes the journal's policy.

If there are circumstances where this is potentially unavoidable, e.g. conference organisers requesting media statements, any publicity should have the written approval of all the authors.

5.2.3 Community / Consumer participation

Grant funding applications may require information on consumer participation. The Raine Study has an established consumer representative group. Agreed standard information on consumer participation should be included as is, or modified to fit grant application requirements (Appendix L).

6. APPENDICES

The following forms are attached in appendices A to K. All forms are available on the Raine Study website.

A. Raine Study Access Agreement

B. Project approval form (P form)

C. Collaboration approval (C form)

D. Project amendment form (P amend form)

E. Collaboration amendment form (C amend form)

F. Access to biological samples (B form)

G. Materials Transfer Agreement (MTA)

H. Manuscript proposal form (M1 form)

I. Manuscript approval form (M2 form)

J. Media release form (M3 form)

K. Acknowledgments

L. Community/Consumer participation

APPENDIX A – Raine Study Data Access Agreement

Western Australian Pregnancy Cohort (Raine) Study

Data Access Agreement

TERMS AND CONDITIONS

Data recipients must be affiliated with one of the Raine Study Special Interest Groups. Approval must be given for the project by the Raine Study Scientific Review Committee prior to receiving data. It is a requirement that the Recipient agree to these Terms and Conditions.

Project Title ……

……

Reference number ……

THIS AGREEMENT is made the between Raine Study Scientific Review Committee acting for the The Western Australian Pregnancy Cohort (Raine) Study and

……

Print name (referred to as "the Recipient") ***Signature*** ***Institution***

On behalf of all other co-investigators who will have access to the requested data as listed below

……

Print name *Signature* *Institution*

……

Print name *Signature* *Institution*

……

Print name *Signature* *Institution*

……

Print name *Signature* *Institution*

The physical location of the data will be *(Please list all Institutions where Recipients will be utilizing the data)*

……

……

Terms and Conditions

1. The Data remains the property of the Raine Study Scientific Review Committee. There is no transfer or licence or implied transfer or licence of rights in the Data from the Raine Study Scientific Review Committee to the Recipient including all intellectual property rights.
2. This Agreement does not restrict the rights of Raine Study Scientific Review Committee to distribute these data to other institutions or to publish any document relating to the data.
3. The Recipient will retain the Data in a secure location and will not permit the Data or any part of it to come into the possession or control of any other organisation or any individual other than those investigators who are indicated on the Research proposal.
4. If there are several collaborators in a particular study, each collaborator using the data must sign the agreement and they are separately responsible for upholding it.
5. The Recipient will ensure that suitable systems are in place for the tracking of the Data while in its possession.
6. Data is provided centrally from the Data Manager to the Researcher. The recipient will not try to link the data set to other Raine datasets held by different recipients or by the same recipient for different projects.
7. The Recipient will use the Data only to carry out the Research as approved by the Raine Study Scientific Review Committee and only for Research that has appropriate ethical approval.
8. Data cannot be transferred between or disclosed to any other person not indicated on the research proposal.
9. The Recipient will not use the Data or any parts thereof for any commercial purpose or any purpose that is subject to consulting or licensing obligations to third parties.
10. The Recipient must notify the Data Manager of any errors found within the dataset for core database maintenance.
11. The Recipient must provide the Data Manager with any new data derived from samples or study subjects at the completion of the study for inclusion in the Raine Data resource.
12. The Recipient must agree to delete all Raine Data files at the completion of the approved project.
13. The Recipient will acknowledge the Raine Study and include as authors individuals identified by the Raine Study Scientific Review Committee who played a key scientific role in the generation of the Data in all publications relating to the Research and Results.
14. All manuscripts pertaining to the Data will be sent to the Raine Scientific Officer (raineadmin-sph@uwa.edu.au) for review prior to submission for publication.
15. The Raine Study Scientific Review Committee accepts no liability in connection with the Recipients use of the Data. To the extent permitted by law the Recipient will indemnify and hold the Raine Study Scientific Review Committee harmless for any damages whatsoever arising from Recipient's use of the Data.

SIGNED for and on behalf of THE RAINE EXECUTIVE Signatue ……

Print Name: ..... Date: ……

SIGNED for and on behalf of RECIPIENT:

(1) Authorised Signature of Recipient ……

Print Name:

..... Date ……..

We require two signed original copies (not photocopies) one for our records

and the other will be return to you.

APPENDIX B – Project Approval form (P form)

P Western Australian Pregnancy Cohort (Raine) Study

Project approval: Approval is required from the Raine Study Scientific Review Committee before any action is taken to commit to any project involving the Raine Study. If the project involves collaboration with new researchers, please also complete a Collaboration form (C form). Please forward all forms to the Raine Study Scientific Officer (raineadmin-sph@uwa.edu.au). If a project or grant application is withdrawn or cancelled, please notify the Raine Study Scientific Officer.

Approval is requested for *(place an 'X' next to all that apply)*

Research proposal	Student project
Research grant application	Access to data
Access to biological samples (*also complete a B-Form)*	Other, *please specify*

Other project:

Project title:

Related approvals: *Related P, B, C form numbers and titles*

Lead investigator: *Title*, *name, position, institution, address, telephone, email (non- student)*

Co-investigator(s): *Title*, *name, position, institution*

Student(s): *Name, institution, student status (e.g. Honours, Masters, PhD), supervisor(s), specific role in project*

Timeframe: *Expected start and completion dates (day/month/year)*

Collaboration with other institutions/cohorts/researchers: *(If new collaborators please complete a C form)***:**

Funding: (*place an 'X' next to all that apply)*						
Obtained Application to funding body No extra funding required						
Funding Body (Name):						
Grant Submission Deadline (Date)						
Principal Grant Holder:						
Administering Institution:						
Funding totals (obtained or applied for): *Raine Study access – 15% of total funds (*place an 'X' next to all that apply)*						
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total**
$						
$ Raine Study*						

Ethics Approval: *Researchers are responsible for obtaining approval from the appropriate Human Research Ethics Committee(s) before data will be released by the Raine Study Scientific Review Committee. Please liaise with Raine Study management in relation to all submissions to Ethics Committees. A copy of the final application, HREC approval and amendments are to be sent to the Raine Study Scientific Officer (place an 'X' next to all that apply)*	
Granted *(committee name, reference number)*	
To be sought *(from which committee)*	
Not necessary *(provide justification)*	

Data Requested: *(place an 'X' next to all that apply)*
Access to existing data
Access to existing genetic data
Collection of new data
Data linkage
Release of samples *(B form required)*

PROJECT DESCRIPTION

Background & rationale: *(~ 100 words)*

Research question, aims and objectives: *(~ 100 words)*

Overview of methods, including study design and statistical methods: *(~ 300 words)*
Statistical justification for sample size and power: *(~ 300 words)*

Data to be used in study: *Summary overview, please detail specific data eg nutrition, mental health, DXA scans (place an 'X' next to all that apply)*

	Questionnaire	Physical assessment	Test results	Details
Antenatal				
Year 1				
Year 2				
Year 3				
Year 5				
Year 8				
Year 10				
Year 14				
Year 17				
Year 20				
Year 22				
Genetic Datasets				
Other Datasets				

By placing an ‘X’ in this box the lead investigator certifies that all investigators listed above have read and agree to the contents of this form.

Lead investigator:	**Date:**

APPENDIX C – Collaboration approval form (C form)

C Western Australian Pregnancy Cohort (Raine) Study

Collaboration approval: Raine Study Scientific Review Committee approval is required for established Raine Study investigators to form collaborations with new researchers or research groups to utilise Raine Study resources.

Project title: *From P form*

Related approvals: *Related P, B form approval numbers*

Collaboration: *Title of project, purpose of collaboration*

Raine Study investigator initiating collaboration: *Title, name, position, institution, address, telephone, email*

Raine Study co-investigator(s): *Title, name, position, institution*

New collaborator(s): *Title, name, position, institution, email*

New student collaborator(s) *Name, institution, student status (e.g. Honours, Masters, PhD), supervisor(s), specific role in project*

Context of collaboration: *< 100 words*

Benefits of collaboration: *< 100 words*

Risks to the Raine Study: *< 100 words, Please outline any potential risks to the Raine Study*
None

By placing an 'X' in this box the lead investigator certifies that all investigators listed above have read and agree to the contents of this form.

Lead investigator:	**Date:**

APPENDIX D – Project amendment form (P amendment form)

Western Australian Pregnancy Cohort (Raine) Study

Project amendment: This form is to be used for any significant changes to existing (approved) Raine projects. It is to be submitted to the Raine Study Scientific Officer (raineadmin-sph@uwa.edu.au)

Project title: *From P form*

P form reference number:

Lead investigator: *Title*, *name, position, institution, address, telephone, email (non- student)*

Co-investigator(s): *Title*, *name, position, institution*

Amendments to project:

Reason for amendments

By placing an 'X' in this box the lead investigator certifies that all investigators listed above have read and agree to the contents of this form.

Lead investigator:	**Date:**

APPENDIX E – Collaboration Amendment form (C amendment form)

Western Australian Pregnancy Cohort (Raine) Study

Collaboration amendment : This form is to used to include additional investigators in to an existing approved collaboration.

Project title: *From P form*

C form reference number:

Lead Investigator: *Title, name, position, institution, address, telephone, email*

Raine Study co-investigator(s): *Title, name, position, institution*

New collaborator(s): *Title, name, position, institution, email*

New student collaborator(s) *Name, institution, student status (e.g. Honours, Masters, PhD), supervisor(s), specific role in project*

Reason for additional collaborator

By placing an 'X' in this box the lead investigator certifies that all investigators listed Above have read and agree to the contents of this form.

Lead investigator:	**Date:**

APPENDIX F – Access to biological samples form (B form)

B Western Australian Pregnancy Cohort (Raine) Study

Access to biological samples: Raine Study Scientific Review Committee approval is required to access any biological samples. Following approval, a completed *Materials Transfer Agreement* must be forwarded to the Raine Study Scientific Officer (raineadmin-SPH@uwa.edu.au) before samples can be released.

Project title: *From P form*

Related approvals: *Related P, C form approval numbers*

Lead investigator: *Title, name, position, institution, address, telephone, email (not a student)*

Co-investigator(s): *Title, name, position, institution*

Student(s): *Name, institution, student status, supervisor(s), specific role in project*

Biological sample(s) requested: *Include follow up, sample required, volume*

Transport of samples: *Provide details of sample transport and the return of remaining samples to the Raine Study.*

Sample viability: *Provide evidence that the analyte(s) is measurable in the biological sample (note that the sample could be up to 23 years old). If necessary, attach publications to support your case.*

If plasma is required, can the proposed assays be done on a plasma sample that has been through the freeze/thaw/freeze process? Please provide details.

Analysis: *Where will the analyses be performed? What is the rationale for performing these analyses at this location?*

Quality control: *Describe the method(s) of quality control (e.g. triplicate testing or CV for testing, control samples)*

Additional analyses: *Is there potential for other tests to be conducted on the sample at the same time?*

Funding: *Detail the costs of analysis and who will be funding these costs (included aliquotting and preparation)*

Sample size: *Please confirm that all proposed analyses will be performed on the whole cohort. This is a requirement for any assessments undertaken on Raine Study biological samples*

Broader use of data: *Please provide evidence of the value of this assay/test to the wider Raine Study research community*

By placing an 'X' in this box the lead investigator certifies that all investigators listed above have read and agree to the contents of this form.

Lead investigator:	**Date:**

APPENDIX G – Material Transfer Agreement (MTA)

Western Australian Pregnancy Cohort (Raine) Study

MATERIAL TRANSFER AGREEMENT

The University of Western Australia (UWA) through The Western Australian Pregnancy Cohort (Raine) Study has collected and bio banked biological research material ('the Material') provided by the study participants and their parents. The Raine Study Executive Committee ('the Committee') of UWA acts as custodians of all data and biological samples.
A Recipient Scientist(s) ('the Investigator(s)') wishes to use certain of the Material held by the Committee for the research project ('the Project') described in the Appendix 1 and as previously approved by the Committee. The Committee is willing to supply the Recipient with the Material to conduct the Research under the terms and conditions of this Agreement.

Internal reference: *Completed by Raine Study*

Date of execution: *Date received by Raine Study*

Recipient scientist(s): *Title, name, position, institution of scientist(s)*

Recipient organisation(s): *Name and address of organisation(s)*

Project for which the materials are supplied: *Please attach project protocol, Appendix 1*

Materials to be supplied: *Please describe materials*

Transmittal fee: *Please provide details fees*

It is agreed by the Committee and the Investigators as follows:

1. The Investigator and other relevant employees of the Recipient involved in the Research have read and will abide by the "Raine Study Data and Biological Samples Access Policy".

2. The Investigator and other relevant employees of the Recipient involved in the Research have read and signed the Raine Study *Data Access Agreement*.

3. The Material remains the property of UWA through the Committee. Any derivatives or data that the Recipients develop from the Material are the property of UWA through the Committee.

4. The Materials and any intellectual property subsisting or in relation to them are the property of UWA through the Committee. The UWA, through the Committee, grants to the recipients a non-exclusive right to use the Materials under the terms and conditions of this agreement. The Recipients must not sell, loan or otherwise provide the Materials to any other party for any purpose with the prior written consent of the Committee.

5. The Recipients' right and license to use the Materials is not transferable. The Recipient will not transfer the Material in whole or in part to third parties.

6. The Recipients must treat as confidential information any Materials or other information provided by the Committee and must take all reasonable and necessary precautions to restrict access to researcher who are directly involved in the Project and who are placed under an obligation to observe the terms of this Agreement.

7. The Materials may only be used strictly within the confines of the Project described in the Appendix 1 to this Agreement, and only for research that has appropriate ethical approval.

8. The Recipient will use the Material in accordance with good laboratory practice and the Recipient will be responsible for complying with all applicable legislation, regulations and relevant standards in relation to the use of the Materials.

9. The Recipient will retain the Material in a secure location on its premises and will not permit the Material or any part of it to come into the possession or control of any organisation or any individual other than those employees who are involved in the Research described in the Appendix 1 under direct supervision of the Recipient. The Recipient will ensure that suitable systems are in place for the tracking of Material while in its possession.

10. The Recipients acknowledge that they will use the Materials at their own risk and agrees to access sole responsibility and liability for the conduct of the Project. To the fullest extent permitted by law, the Committee supplies the Materials without any warranties, express or implied, including without limitation any warranties of merchantability or fitness for a particular purpose.

11. To the extent permitted by the laws of its state, the Recipients agree to indemnify and keep indemnified the Committee and its officers, employees and agents against any and all damages, expenses, claims, demands, suits or other liability arising from the Recipients use or disposal of materials.

12. The Recipient must return (at their expense) to the Committee or, at the Committee's request, arrange (at their expense) the disposal or destruction of all remaining or unused Material.

13. The Recipients must keep the Committee informed of the results of the Research ("Results"). The Recipients must provide to the Committee copies of any reports and outlines of any results in relation to the research and experimentation conducted on the Materials.

14. UWA, through the Committee, will own all Results directly relating to the Study Participants for the purposes of incorporation into the Raine Study resource. The Recipient will provide the Committee with a fully documented electronic copy of the Results.

15. The Recipients agree to acknowledge the Committee and to appropriately cite by authorship (in accordance with the Australian Code for the Responsible Conduct of Research published by the National Health and Medical Research Council) any responsible Committee members or its representative in any publications or presentations which result from this project.

16. During and after the term of this Agreement, the Recipient Scientist must provide the Committee (or it representative) with copies of all manuscripts before submission for publication or disclosure, in compliance with the Terms of the Raine Study Access to Data and Biological Samples Policy. *"All manuscripts are to be sent to the Raine Secretariat prior to submission for publication. Papers will be reviewed to confirm internal consistency within publications (e.g. sample size, years of cohort review), publication quality and appropriate acknowledgments. The manuscript review process will take 7-14 days to complete."*

17. Unless terminated previously, the term of this Agreement shall be three (3) years from date of execution of this Agreement.

18. The Committee may terminate this Agreement at any time by giving 30 days notice to the Recipient.

19. This Agreement may only be amended in writing, signed by the parties.

20. This Agreement supersedes all prior communications between the parties.

AGREED BY THE PARTIES through their authorised signatories
Signed for and on behalf of the COMMITTEE

Signed: .....

Name:

Position:

Date:

Signed for and behalf of the RECIPIENT
Authorised signatory of Recipient .....

Name:

Position:

Date:

Signature of Investigator
Signed: .....

Name:

Position:

Date:

We require two signed copies, one for our records and the other we will return to you

APPENDIX H – Manuscript proposal form (M1 form)

M1 Western Australian Pregnancy Cohort (Raine) Study

Manuscript proposal: Approval from the Raine Study secretariat is required in order to propose a new manuscript and gain access to data (M1 form), submit a prepared manuscript to a journal (M2 form) and release a media statement concerning a manuscript (M3 form). **All manuscripts must relate to a previously approved project**.

Title: *Title of proposed manuscript*

Related approvals: *Related P, B form approval numbers*

Corresponding author: *Title, name, position, institution, address, telephone, email*

Co-authors: *Title, name, position, institution*

Proposed journal: *Journal name and rank in field*

Background: *Details of project aim, background, justification, what is novel*

Study design and statistical methods: *Details of study design, statistical analysis, nominated statistician*

Data Required: *Summary overview, please detail specific data e.g. nutrition, mental health, blood test results*

	Questionnaire	Physical assessment	Test results	Details
Antenatal				

Year 1				
Year 2				
Year 3				
Year 5				
Year 8				
Year 10				
Year 14				
Year 17				
Year 20				
Year 22				
Genetic Datasets				
Other Datasets				

By placing an 'X' in this box the lead investigator certifies that all investigators listed above have read and agree to the contents of this form.

Corresponding author:	**Date:**

APPENDIX I – Manuscript approval form (M2 form)

M2 Western Australian Pregnancy Cohort (Raine) Study

Manuscript approval: All completed manuscripts (together with this form) must be sent to the Raine Study Secretariat (raineadmin-SPH@uwa.edu.au) prior to submission for publication. The secretariat reviews the manuscript for content, context, authorship, methodology, consistency of reporting and acknowledgements. Please complete a lay summary of the manuscript (page 2).

Title: *Title of manuscript*

Related approvals: *Related P, B form approval numbers*

M1 form reference number : *From M1- review approval*

Corresponding author: *Title, name, position, institution, address, telephone, email*

Co-authors: *Title, name, position, institution*

Journal: *Journal name and rank in field*

Lay Summary: Researchers are requested to prepare a short six point summary of the completed manuscript. The purpose of these plain language summaries is to make the Raine Study findings accessible and interpretable by the general public and available on the Raine Study's website. The lay summary will be made available on the website after the article is fully published.

Lay title: *Brief plain language title for the paper*

Keywords: *4 or so plain language keywords for the general public to search for the paper or related content*

What is already known about this subject:
• Background point one – e.g. introduce the general topic and state why it is important • Background point two – e.g. state the specific issue being addressed in this study. • Background point three – e.g. state what is the gap in knowledge and/or why it is important to understand this.

What this Raine Study publication adds:
• Point four – e.g. what Raine data was used (age of collection, method of collection, etc) and provide a simple statement of what the main finding is • Point five – e.g. provide some other important findings • Point six – e.g. describe the impact and/or significance of these findings

By placing an 'X' in this box the lead investigator certifies that all investigators listed above have read and agree to the contents of this form.

Lead investigator:	**Date:**

APPENDIX J – Media release form (M3 form)

M3 Western Australian Pregnancy Cohort (Raine) Study

Media release : All media releases must be sent to the Raine Study secretariat and approval received prior to dissemination.

Title: *Title of manuscript*

M1 form reference number: *From M1- review approval*

M2 review date: *From M2-review approval – date of approval*

Corresponding author: *Title, name, position, institution, address, telephone, email*

Journal: *Journal name and rank in field*

Media release: *Insert a copy of the media release*

All authors are encouraged to have their media release reviewed by someone with expertise in media/science communication. *Please list name and affiliation of this individual*

By placing an 'X' in this box the lead investigator certifies that all investigators listed above have read and agree to the contents of this form.

Corresponding author:	**Date:**

APPENDIX K – Raine Study acknowledgements

Western Australian Pregnancy Cohort (Raine) Study

Raine Study – Acknowledgments

The following groups are to be included in all acknowledgements:

- The Raine Study participants and their families
- The Raine Study Team for cohort co-ordination and data collection
- The NH&MRC for their long term contribution to funding the study over the last 25 years (unless individual NH&MRC grants are acknowledged).

The following Institutions must be included in all acknowledgements for providing funding for Core Management of the Raine Study

- The University of Western Australia (UWA)
- Curtin University
- The Telethon Kids Institute
- Raine Medical Research Foundation
- UWA Faculty of Medicine, Dentistry and Health Sciences
- Women and Infants Research Foundation
- Edith Cowan University

If data from a particular cohort review is utilised the following specific funding bodies must be acknowledged

Antenatal data

- The Raine Medical Research Foundation

Maternal blood samples during pregnancy or cord blood

- NH&MRC
- Women and Infants Research Foundation

1, 2, 3, 5, 8, 10 year cohort reviews

- NH&MRC
- The Raine Medical Research Foundation

14 year follow up

- NH&MRC (Sly et al, ID 211912)
- NH&MRC Program Grant (Stanley et al, ID 003209)
- The Raine Medical Research Foundation

Menstruation in Teenager Study (PCOS Data)

- NH&MRC (Hickey et al, 403968)

17 year follow up

- *Always include NH&MRC Program Grant (Stanley et al, ID 353514)*

Biological specimens from the 14 and 17 year cohort reviews

- NH&MRC (Beilin et al, ID 403981)

Cogstate and Functional MRI data

- NH&MRC (Foster et al, ID 458623)

Spinal pain, posture data

- NH&MRC (Straker et al, ID 323200)

Basal HPA axis data 17 years

- NH&MRC (Foster et al, ID 458623)
- CIHR (Lye et al, MOP-82893)

DNA or GWAS Data

- NH&MRC (Palmer et al, ID 572613)
- NH&MRC (Beilin et al, ID 403981)
- CIHR (Lye et al, MOP-82893)

Trier Social Stress Test data

- CIHR (Lye et al, MOP-82893)

Raine Study 20 year Follow up

Non alcoholic liver disease

- NH&MRC (Adams et al, ID634445)

Risky Behaviour

- NH&MRC (Skinner et al, ID634509)

Male Fertility Study

- NH&MRC (Hart et al, ID 634457) Male Fertility Study

DXA Scans

- CIHR (Lye et al, MOP-82893)

Eye Data

- NHMRC (Mackey et al, ID 1021105)
- CIHR (Lye et al)
- Lions Eye Institute
- Australian Foundation for the Prevention of Blindness
- Alcon Research Institute
- Telethon
- Ophthalmic Research Institute of Australia

EXAMPLE ACKNOWLEDGEMENT FOR STUDY USING 20-YEAR DATA

We are grateful to the Raine Study participants and we thank the Raine Study and Lions Eye Institute research staff for cohort coordination and data collection. The core management of the Raine Study is funded by The University of Western Australia (UWA), Curtin University, The Telethon Kids Institute, Raine Medical Research Foundation, UWA Faculty of Medicine, Dentistry and Health Sciences, Women and Infants Research Foundation and Edith Cowan University. The 20-year eye follow-up of Raine Study was funded by NHMRC Grant 1021105, Ophthalmic Research Institute of Australia (ORIA), Alcon Research Institute, Lions Eye Institute and the Australian Foundation for the Prevention of Blindness. The National Health and Medical Research Council Project #1022134 (2012-2014) funded the serum 25(OH)D assays that were conducted by RDDT in Melbourne Victoria, Australia.

Raine Study 22year follow up

- The Centre for Sleep Science, School of Anatomy, Physiology & Human Biology, UWA

Asthma testing

- NH&MRC (Hall et al, ID 1021858)

Sleep Studies

- NH&MRC (Eastwood et al, ID 1027449

Sedentary behavior and physical activity

- NH&MRC (Straker et al, ID 1044840)

Work

- Safework Australia

Blood assays

- WADOH, Future Health WA G06302 (Eastwood et al)

EXAMPLE ACKNOWLEDGEMENT FOR STUDY USING 22-YEAR DATA

We would like to acknowledge the Raine Study participants for their ongoing participation in the study, the Raine Study Team for study co-ordination and data collection, the UWA Centre for Science for utilisation of the facility and the Sleep Study Technicians. We would like to acknowledge the University of Western Australia (UWA) , Curtin University, the Raine Medical Research Foundation, the UWA Faculty of Medicine, Dentistry and Health Sciences, the Telethon Kids Institute, the Women and Infants Research Foundation (King Edward Memorial Hospital) and Edith Cowan University for providing funding for the Core Management of the Raine Study. The 22 year Raine Study follow-up was funded by NHMRC project grants 1027449, 1044840 and 1021855. Funding was also generously provided by Safework Australia.

BIOLOGICAL SAMPLES

Where access to biological samples has been provided or biological samples assay data have been used, please acknowledge the in-kind support provided by the following institutions for sample storage and curation.

- UWA School of Women and Infants Health, King Edward Memorial Hospital
- UWA School of Medicine and Pharmacology, Royal Perth Hospital
- DNA bank at Sir Charles Gairdner Hospital
- Telethon Kids Institute

APPENDIX L – Information on community and consumer participation

Western Australian Pregnancy Cohort (Raine) Study

Grant Applications – Community and Consumer Participation

Investigators are required to address the following question in most NH&MRC applications:

2.8 Does this research involve consumers and/or community participation?

If yes, describe how you will ensure that:

1. Research participants will have access to their own results and how you will be accountable to participants for the overall results of research.
2. Consumers will be involved in this research and how you will communicate the results of the research to participants and the community. (1000 characters)

Suggested response

2.8.1 The Raine Study has strict confidentiality protocols. Participants are provided with individual results on request and everyone is routinely sent biological sample test results. The Raine Study informs participants of individual results where it would be beneficial to their health and wellbeing to have this information and where there may be health implications for themselves and their family. We have established protocols in place and access to supportive networks in the clinical community where necessary. (438 characters)

2.8.2 The Raine Study has an established consumer representative group. They meet bi-monthly with Raine Study Staff and Investigators and provide an important consultant and collaborative role on research proposals and cohort management issues. The Group has control over the content of communication with study members (newsletters, information sheets, results, cards, competitions, websites, and meetings). They are consulted on areas for future research. The Raine Study has a liaison officer for communication and cohort retention.

Overall results are communicated to participants through quarterly newsletters, booklets for participants and the wider community promoting healthy outcomes [ref 1], and the Raine Study Website providing access to information, publications and media releases for consumers and the wider community.[ref 2]

For new research proposals, workshops are held with the Investigators, the consumer group and a randomly selected group of participants (20 to 25) discussing the proposal, participant involvement and the dissemination of results.

Cohort retention through consumer involvement and consultation is paramount to the success of the Raine Study. The Raine Study fee contributes towards costs of consumer involvement. (1065 characters)

1. Oddy WH, O'Sullivan T, Robinson M, Monterio M, Mountain J, All about me – facts and figures from the Raine Study, TICHR, Booklet 2008
2. www.rainestudy.org