



## RESEARCHER ENGAGEMENT POLICY

The Western Australian Pregnancy Cohort (Raine) Study

An Unincorporated Joint Venture partnership involving:



# Introduction

The Western Australian Pregnancy Cohort (Raine) Study ([www.rainestudy.org.au](http://www.rainestudy.org.au)) was established 1989-1991 “to develop a large cohort of Western Australian children studied from 18 weeks’ gestation to ascertain the relative contributions of familial risk factors, fetal growth, placental development and environmental insults to outcomes in infancy and to the precursors of adult morbidity. This cohort, with complete intrauterine, perinatal and childhood data will enable evaluation of the interaction between these factors, subsequent lifestyle patterns and environmental exposures which contribute to ill health during life.” The initial cohort study was supported by combining funds from The Raine Medical Research Foundation with funds awarded by the National Health and Medical Research Council of Australia.

The Raine Study is now one of the largest and oldest successful prospective cohorts of pregnancy, childhood, adolescence and now adulthood to be carried out anywhere in the world. Since its genesis in 1989, it has made a substantial impact in terms of discovery and practice. For example over 450 peer-reviewed scientific papers have been published using the Raine Study data and Raine Study discoveries have informed health policy and clinical practice (see website for details). The study was initially focused on understanding the developmental origins of health and disease, but has since evolved into a multi-generational life-course study taking into account the multiple interacting domains of genetics, phenotypes (cardiometabolic, respiratory, immunological, hormonal, musculoskeletal, psychological, vision and hearing, body composition and growth), behaviours (physical activity, sedentary behaviour, sleep, diet, drug use, risk taking), the environment (sunlight, chemical exposures, spatial environment) and health, social (education, work) and developmental outcomes. Details of the questionnaire data, clinical assessment data and biosample data and materials collected since inception on the original parents (Generation 1), the original fetuses (Generation 2) and the offspring of the original fetus (Generation 3) are also available on the website.

The Raine Study is now owned and governed by an Unincorporated Joint Venture partnership between the University of Western Australia (central agent), Curtin University, Edith Cowan University, Murdoch University, the University of Notre Dame, the Women’s and Infants’ Research Foundation and Telethon Kids Institute with ongoing financial support from the Raine Medical Research Foundation.

## **The Researcher Engagement Policy**

The purpose of the Raine Study is to “improve human health and well-being by studying the life-course of a cohort of Western Australians from before birth onwards.” Researcher engagement with the Raine Study that is aligned with the purpose of the study is encouraged. This document sets out the policy for such engagement including the conditions and rules for utilising Raine Study resources and expected behaviour.

## Definitions

For the purposes of this policy:

1. “Participants” refers to all members of families who have been invited to contribute data to the Raine Study. This includes the mothers and fathers initially recruited to the study (Generation 1), the original fetuses (Generation 2), the offspring of the original fetuses (Generation 3), and the grandparents of the original fetuses (Generation 0).
2. “Researcher(s)” refers to all individuals seeking to conduct research using any Raine Study resources.
3. “Raine Study” refers to the entity owned and governed by the Raine Study Unincorporated Joint Venture.
4. “Raine Study financial partners” refers to the organisations currently contributing to the Raine Study Unincorporated Joint Venture.
5. “Scientific Review Committee” refers to the committee established by the Raine Study and tasked with ensuring the scientific quality and integrity of Raine Study activities.
6. “Special Interest Groups” are established by the Raine Study as groups of researchers with responsibilities to develop and utilise relevant domains of data.
7. “Resources” includes all Raine Study participants, data, biosamples, facilities, staff and reputation.
8. “Data” includes all information (in an anonymised form) available for use in approved projects by approved researchers, relating to the participants’ demographic, genetic, phenotypic, behavioural, environmental, and work and education outcomes. This includes data derived from biosample analyses, questionnaires, clinical assessments (including physical assessments and scans) and from linked databases.
9. “Biosample” includes all biological specimens collected from the participants. This includes blood, DNA, urine, faeces, hair and teeth.
10. “Analytical Dataset” refers to de-identified Raine Study data supplied to approved researchers for an approved project.
11. “Raine Study Team” refers to the staff employed by the Raine Study who manage all contact with participants and all data collection from participants.
12. “Policy” refers to this Researcher Involvement Policy.

**This policy will be effective from the 1<sup>st</sup> August 2018 and will be applied to all current and future projects.**

*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](http://www.rainestudy.org.au)). It is the responsibility of the researchers to be aware of and adhere to any changes.*

## Table of Contents

1.	General Researcher Engagement Principles .....	5
2.	Project Application Review and Approval Principles.....	6
2.1	General project application considerations.....	6
2.2	Considerations for all researchers planning a project .....	6
2.3	Considerations for grant applications .....	6
2.4	Considerations for projects lead by researchers based at a UJV partner organisation.....	7
2.5	Considerations for projects lead by researchers based at other organisations .....	7
2.6	Considerations for student researchers .....	8
2.7	Considerations for projects only involving use of existing data.....	8
2.8	Considerations for projects involving use of existing biosamples .....	8
2.9	Considerations for projects involving collection of new data from participants .....	8
2.10	Considerations for projects involving collection of new biosamples from participants.....	8
3.	Project Conduct Principles .....	9
3.1	General project conduct considerations .....	9
3.2	Considerations for obtaining data.....	9
3.4	Considerations for obtaining biosamples.....	9
3.5	Considerations for new data collection/new biosample collection.....	10
4.	Project Reporting Principles.....	10
4.1	General project reporting considerations .....	10
4.2	Considerations for manuscript idea and submission approval.....	10
4.4	Considerations for media release submission and approval .....	11
4.3	Considerations for presentations (scientific conference, professional seminar, community talk)	
	11	
5.	Scientific Review Committee review of project proposals.....	12
6.	Website links .....	12

## 1. General Researcher Engagement Principles

1. The purpose of the Raine Study is “to improve human health and well-being by studying the life-course of a cohort of Western Australians from before birth onwards.”
2. Raine Study resources will be managed in line with the agreed purpose to optimise their utilisation and value for research and public benefit.
3. All researchers must abide by the Australian Code for the Responsible Conduct of Research (<https://www.nhmrc.gov.au/guidelines-publications/r41>) when using Raine Study resources. This includes:
  - a. maintaining high standards of intellectual honesty and integrity, and scholarly and scientific rigor;
  - b. declaring any potential perceived conflicts of interest;
  - c. reporting research responsibly;
  - d. respecting participants; and
  - e. respecting the community at large.
4. The Raine Study reserves the right to refuse a researcher’s access to Raine Study resources in the case of a breach of this policy or the Australian Code for the Responsible Conduct of Research in relation to the Raine Study.
5. Projects conducted using Raine Study resources must be bona fide research (<https://www.mrc.ac.uk/research/policies-and-guidance-for-researchers/>). This normally includes:
  - a. the intention to generate new knowledge using rigorous scientific methods;
  - b. the intention to publish findings as thoroughly and quickly as practicable, following peer-review by the scientific community;
  - c. the intention to interpret and translate findings to improve human health and well-being through policy and practice; and
6. Commercial research use of Raine Study resources may be considered, following individual case scrutiny by the Raine Study Directors, Scientific Review Committee and UJV Board.
7. All projects conducted using Raine Study resources must be compatible with the purpose of the Raine Study.
8. Projects should involve collaboration with an existing member of a Raine Study Special Interest Group who is employed at one of the supporting partner organisations.
9. Where possible, projects should facilitate building research capacity in Western Australia.
10. Prior to commencement all research projects must have:
  - a. Raine Study approval; and
  - b. ethics approval.

## 2. Project Application Review and Approval Principles

### 2.1 General project application considerations

1. The detailed processes for applying for approval to conduct a project using Raine Study resources are outlined in the Raine Online Submission System (ROSS) guide on the Raine Study website (<https://www.rainestudy.org.au/wp-content/uploads/2018/06/ROSS-Guide-June-2018.pdf>).
2. Templates for information required for project applications in ROSS are provided on the Raine Study website (<https://www.rainestudy.org.au/index.php/for-researchers/ross-raine-online-submission-system/ross-forms/>). These templates are ideal for emailing between collaborators when preparing a project – although the final submission needs to be via ROSS.

### 2.2 Considerations for all researchers planning a project

1. Researchers must normally be employed at a recognised research organisation with clear governance and commitment to conducting bone fide research.
2. Researchers must declare any potential conflicts of interest in any project.
3. Researchers should carefully consider the scientific rigor, likely importance of findings, expertise of the research team, feasibility, and potential impact on participants whilst planning any project.
4. Researchers are encouraged to involve participant representatives at an early stage in project planning.
5. Researchers must consider how the resources needed to conduct any project in a timely manner can be acquired. All necessary resources need to be in place before full approval to conduct a project will be provided.
6. All research project costs need to be budgeted and approved prior to commencement of a project. Budgets must clearly show what funding will be managed by the Raine Study and what will be managed by the project research team.
7. Inclusion of researchers in a project team should be solely on the basis of merit.
8. The research team listed should include all those contributing intellectually to the research project including statisticians. Listing as a team member does not necessarily mean authorship on all publications arising from a project (see section 4.1).
9. Researchers who have contributed substantially to the acquisition of resources will have priority access to those resources for two years after the resources are available for use, following which for the next five years they would normally be consulted about potential involvement in other projects planning to use those resources.
10. All contracts involving Raine Study resources must be approved by the Raine Study and would normally be with the Raine Study directly, not the project research team.

### 2.3 Considerations for grant applications

1. Projects must have provisional approval from the Scientific Review Committee prior to grant applications being submitted to funding agencies.

2. All grant agency applications need to include requests to support ongoing curation of the Raine Study. This is currently set at 15% of the total grant value, to a maximum of \$75,000. Grants for less than \$25,000 can use a reduced rate of 5% and grants less than \$50,000 can use a reduced rate of 10%.
3. Where the Raine Study resources represent only a part of a larger study, then Raine Study data fees may be reduced in proportion to the contribution to the overall study. Any potential reduction in Raine Study fees will need to be negotiated before project approval and will take into consideration the capacity of the funding agency to provide funds, the value of the project to UJV partner researchers and to capacity building in Western Australia.
4. All grant agency applications should cover the total cost of research projects, including any data or biosample collection and biosample analysis.
5. Grant funded projects can only be commenced once all final protocols, budgets, resources and ethics approvals have been obtained and approved by the Raine Study.

#### 2.4 Considerations for projects lead by researchers based at a UJV partner organisation

1. The project lead should ideally be a researcher who has previously participated in at least one Raine Study project (from application through to manuscript submission).
2. Existing data will normally be provided to researchers based at a partner organisation at no cost. Where very large or complex data requests require unusually large time commitments by Raine Study staff or collaborators to prepare analytic data sets a fee will be negotiated with researchers prior to project approval.

#### 2.5 Considerations for projects lead by researchers based at other organisations

1. Projects can be lead by researchers employed at organisations which are not financial partners of the Raine Study.
2. Research projects lead by researchers from organisations which are not financial partners of the Raine Study should include in the project team investigator(s) who are employed at a UJV partner organisation.
3. Research projects lead by researchers from organisations which are not financial partners of the Raine Study should ideally include in the project team investigator(s) who has previously participated in at least one Raine Study project (from application through to manuscript submission).
4. Research projects conducted in organisations which are not financial partners of the Raine Study will need to pay for access to existing data and other Raine Study resources and support. Costs will be negotiated prior to project approval and will take into consideration; the value of the data provided (e.g. the number of variables requested, cost of obtaining the variables, age of the variables, etc), the capacity of the non-UJV researchers and funding organisations to provide funds, the value of the project to UJV partner researchers and to research capacity building in Western Australia.
5. Researchers who have moved from a partner organisation to another organisation may negotiate reduced project costs in consideration for prior contributions to Raine Study resource development.

## 2.6 Considerations for student researchers

1. Student projects should be submitted as a separate project for approval.
2. Student projects must nominate who are the experienced researchers who will be responsible for supervising the project and student.
3. The project lead for a student project should be the main supervisor.
4. As with other projects, at least one investigator should be employed at a UJV partner organisation and ideally have previously participated in at least one Raine Study project (from application through to manuscript submission)
5. As with other researchers, students enrolled at a partner institution will not normally need to pay for access to existing data.
6. Students enrolled at an institution which is not a financial partner of the Raine Study will need to pay a fee to use existing data. The fee for accessing Raine Study resources must be negotiated prior to project approval.

## 2.7 Considerations for projects only involving use of existing data

1. Full approval can be given by the Scientific Review Committee as long as all resource requirements are in place.

## 2.8 Considerations for projects involving use of existing biosamples

1. Researchers must provide detailed information on biosample required, curation history requirements, analysis laboratory credentials, analysis method efficiency, reliability and validity, and relative merit of utilising these finite resources in the application.
2. Provisional approval can be given by the Scientific Review Committee to enable the research project team to work with the Raine Study to finalise protocols and materials transfer agreements.

## 2.9 Considerations for projects involving collection of new data from participants

1. Provisional approval can be given by the Scientific Review Committee to enable research project team to work with the Raine Study to finalise protocols.

## 2.10 Considerations for projects involving collection of new biosamples from participants

1. Researchers must provide detailed information on biosample required, collection protocol requirements, analysis laboratory credentials and analysis method efficiency, reliability and validity in the application.
2. Templates for information required for ROSS are provided on the Raine Study website (<https://www.rainestudy.org.au/index.php/for-researchers/ross-raine-online-submission-system/ross-forms/>). These templates are ideal for emailing between collaborators when preparing a project – although the final submission needs to be via ROSS.

3. Provisional approval can be given by the Scientific Review Committee to enable the research project team to work with the Raine Study to finalise protocols and materials transfer agreements.

## 3. Project Conduct Principles

### 3.1 General project conduct considerations

1. The detailed processes for conducting a project using Raine Study resources are outlined in Raine Online Submission System guide on the Raine Study website (<https://www.rainestudy.org.au/wp-content/uploads/2018/06/ROSS-Guide-June-2018.pdf>).
2. Projects can only commence once they have received **full approval** from the Raine Study Scientific Review Committee and have all required ethics approvals.
3. Any changes to an approved project, such as a changes in research team or project focus, must be approved by the Raine Study.

### 3.2 Considerations for obtaining data

1. Prior to gaining access to any data all researchers for a project must agree to the terms and conditions. These include:
  - a. Recognising data are provided for the specific project only, and are not to be used for any other purpose (including other approved projects),
  - b. Maintaining a high level of data security and confidentiality,
  - c. Returning derived variables generated as part of the project in a timely manner, with variable descriptions and coding guide.
2. All data for use in projects must come directly from the Raine Study.
3. All data requests must nest within an approved project.

### 3.4 Considerations for obtaining biosamples

1. Prior to gaining access to any biosamples all researchers for a project must agree to the terms and conditions. These include:
  - a. Recognising biosamples are provided for the specific project only, and are not to be used for any other purpose,
  - b. Maintaining a high level of security and confidentiality,
  - c. Returning derived variables generated as part of the project in a timely manner, with variable descriptions and coding guide.
  - d. Returning any unused materials.
2. Prior to gaining access to any biosamples all organisations who will handle the biosamples must sign a Material Transfer Agreement. The Raine Study team will coordinate all Material Transfer Agreements.
3. All biosample requests must nest within an approved project.

### 3.5 Considerations for new data collection/new biosample collection

1. Following provisional approval of a project to collect new data and/or biosamples by the Scientific Review Committee, the project team must work with the Raine Study to develop detailed agreed protocols for data/biosample collection and immediate processing.

## 4. Project Reporting Principles

### 4.1 General project reporting considerations

1. The detailed processes for reporting on a project using Raine Study resources are outlined in Raine Online Submission System guide on the Raine Study website (<https://www.rainestudy.org.au/wp-content/uploads/2018/06/ROSS-Guide-June-2018.pdf>).
2. All project investigators must abide by authorship standards as outlined in the Australian Code for the Responsible Conduct of Research (<https://www.nhmrc.gov.au/guidelines-publications/r41>) and the International Committee of Medical Journals Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (<http://www.icmje.org/recommendations/>). These include:
  - reporting with respect for participants and to maintain confidentiality;
  - ensuring findings are reported fairly, accurately and fully;
  - appropriately citing prior publications and the work of others;
  - promoting scientific impact; and
  - promoting translation to practice and policy and public awareness.
3. Authorship is based on the following four criteria (<https://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorship> & <http://www.icmje.org/recommendations/>):
  - “Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
  - Drafting the work or revising it critically for important intellectual content; AND
  - Final approval of the version to be published; AND
  - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.”

### 4.2 Considerations for manuscript idea and submission approval

1. Approval from the Raine Study must be obtained prior to commencing work on a manuscript (Manuscript Proposal (MP)).
2. All MP approvals must nest within an approved project.
3. Approval from the Raine Study must be obtained prior to submitting a manuscript to a journal (Manuscript Submission (MS)). Manuscripts ready for submission and a lay summary in the specified format are required for MS review. Manuscripts will be checked for similarity/plagiarism, potential negative impact on the cohort, and appropriate acknowledgements.

4. Details of appropriate acknowledgements are provided on the Raine Study website (: [https://www.rainestudy.org.au/wp-content/uploads/2018/01/Raine-Study-Acknowledgements\\_20180129.pdf](https://www.rainestudy.org.au/wp-content/uploads/2018/01/Raine-Study-Acknowledgements_20180129.pdf)).
5. All MS approvals must nest within an approved project and relate to a prior MP approval.
6. Templates for MP and MS information required for ROSS are provided on the Raine Study website (<https://www.rainestudy.org.au/index.php/for-researchers/ross-raine-online-submission-system/ross-forms/>). These templates are ideal for emailing between collaborators when preparing a project – although the final submission needs to be via ROSS.

#### 4.4 Considerations for media release submission and approval

1. Researchers are encouraged to promote translation of discoveries by utilising mass media including social media.
2. Research findings should only be discussed in the media following peer review. Researchers must abide by any embargo required by the paper publisher (typically until paper is published).
3. Research findings must be discussed in the media in a manner that is sensitive to cohort, accurate, and in line with the purpose of the Raine Study.
4. Approval from the Raine Study must be obtained prior to any media release (MR). A draft of the media release should be submitted to the Raine Study for review, and should acknowledge all UJV partners ([https://www.rainestudy.org.au/wp-content/uploads/2017/10/Media-Release-Guidelines\\_20171023.pdf](https://www.rainestudy.org.au/wp-content/uploads/2017/10/Media-Release-Guidelines_20171023.pdf)).
5. MR approvals would typically be related to an existing MS approval.
6. Templates for MR information required for ROSS are provided on the Raine Study website (<https://www.rainestudy.org.au/index.php/for-researchers/ross-raine-online-submission-system/ross-forms/>). These templates are ideal for emailing between collaborators when preparing a project – although the final submission needs to be via ROSS.

#### 4.3 Considerations for presentations (scientific conference, professional seminar, community talk)

1. Researchers are required to maintain a record of all presentations on Raine Study research and provide a summary when requested.

## 5. Scientific Review Committee review of project proposals

- Scientific Review Committee members must declare any potential conflicts of interest with project proposals.
- Research proposals will be reviewed for scientific rigor, likely importance of findings, expertise of research team, feasibility, and impact on participants.
- Where insufficient expertise exists within the Scientific Review Committee, independent scientific reviews will be obtained.

## 6. Website links

- Australian Code for the Responsible Conduct of Research: <https://www.nhmrc.gov.au/guidelines-publications/r41>
- Bona fide research guidelines: <https://www.mrc.ac.uk/research/policies-and-guidance-for-researchers/>
- International Committee of Medical Journals Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals: <http://www.icmje.org/recommendations/>
- Authorship guidelines: <https://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorship>
- ROSS guide: <https://www.rainestudy.org.au/wp-content/uploads/2018/06/ROSS-Guide-June-2018.pdf>
- Acknowledgements guidelines: [https://www.rainestudy.org.au/wp-content/uploads/2018/01/Raine-Study-Acknowledgements\\_20180129.pdf](https://www.rainestudy.org.au/wp-content/uploads/2018/01/Raine-Study-Acknowledgements_20180129.pdf)
- Nomenclature guidelines: [https://www.rainestudy.org.au/wp-content/uploads/2017/10/Nomenclature-guidelines\\_20171023.pdf](https://www.rainestudy.org.au/wp-content/uploads/2017/10/Nomenclature-guidelines_20171023.pdf)
- Media release guidelines: [https://www.rainestudy.org.au/wp-content/uploads/2017/10/Media-Release-Guidelines\\_20171023.pdf](https://www.rainestudy.org.au/wp-content/uploads/2017/10/Media-Release-Guidelines_20171023.pdf)

End of Document