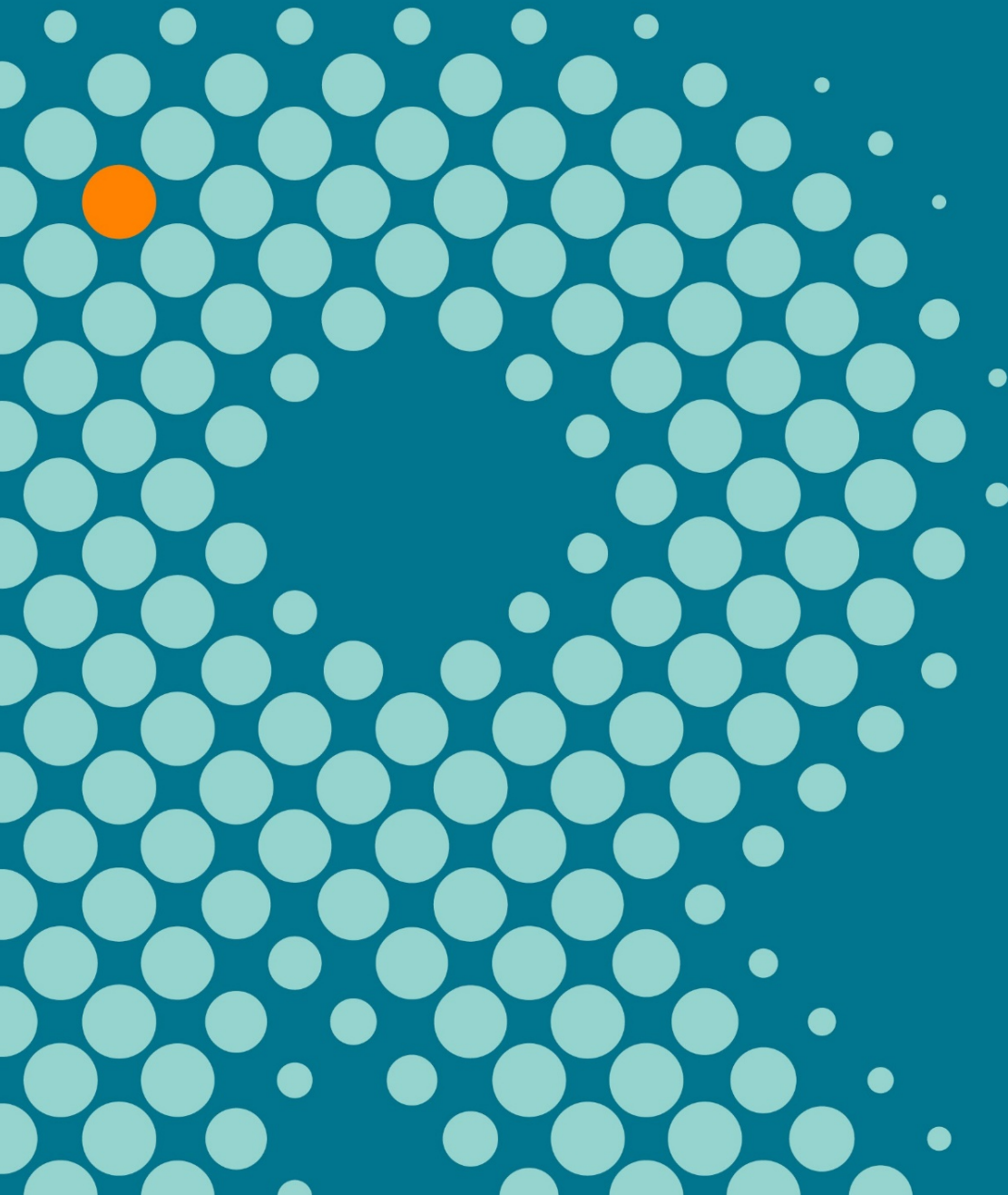


Researcher Engagement Policy

The Raine Study





Introduction

The Raine Study 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 1989-1991, it has made a substantial impact in terms of discovery and practice. For example over 500 peer-reviewed scientific papers have been published using the Raine Study data and the Raine Study discoveries have informed improved health policy and clinical practice (see [the Raine Study 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 biosamples data and materials collected since inception on the original parents (Generation 1 – Gen1), the original babies (Generation 2 – Gen2), the offspring of Generation 2 (Generation 3 – Gen3), and the grandparents of Generation 2 (Generation 0 – Gen0) are also available on [the Raine Study website](#).

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

The Researcher Engagement Policy

The mission of the Raine Study is “to improve lifelong health and quality of life through ground-breaking, impactful research that examines influences, pathways and outcomes from before birth and throughout life’s course.” Researcher engagement with the Raine Study that is aligned with this mission is encouraged. This document sets out the policy for such engagement including the conditions and rules for utilising the 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 (Gen1), the original babies (Gen2), the offspring of Generation 2 (Gen3), and the grandparents of Generation 2 (Gen0).
2. “Researcher(s)” refers to all individuals seeking to conduct research using any Raine Study resources.
3. “The Raine Study” refers to the entity owned and governed by the Raine Study Unincorporated Joint Venture.
4. “The Raine Study UJV financial partners” refers to the organisations currently contributing to the Raine Study Unincorporated Joint Venture.
5. “Institutional Associate member” refers to non-financial partner organisations formally approved as financial contributors to the Raine Study.
6. “Scientific Management Committee” refers to the committee established by the Raine Study and tasked with managing science related activities for the Raine Study.
7. “Scientific Review Committee” refers to the committee established by the Raine Study and tasked with ensuring the scientific quality and integrity of the Raine Study activities.
8. “Special Interest Groups” are established by the Raine Study as groups of researchers with responsibilities to develop and utilise relevant domains of Raine Study data.
9. “Resources” includes all the Raine Study participants, data, biosamples, facilities, staff and reputation.
10. “Data” includes all information (in an anonymised form) available for use in approved projects by approved researchers, relating to the Raine Study 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.
11. “Biosamples” includes all biological specimens collected from the Raine Study participants. This includes blood, DNA, urine, faeces, hair and teeth.
12. “Analytical Dataset” refers to de-identified Raine Study data supplied to approved researchers for an approved project.
13. “The Raine Study Team” refers to the staff employed by the Raine Study who manage all contact with participants and all data collection from participants.
14. “Policy” refers to this Researcher Engagement Policy.

This policy will be effective from the 1st August 2019 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](#). It is the responsibility of the researchers to be aware of and adhere to any changes.



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1. General Researcher Engagement Principles

1. The mission of the Raine Study is “to improve lifelong health and quality of life through ground-breaking, impactful research that examines influences, pathways and outcomes from before birth and throughout life’s course.”
2. The Raine Study also operates under four core values:
 - **Committed** – We are committed to innovation, discovery and scientific rigour. Our staff, researchers and participants do what they do for the greater good.
 - **Collaborative** – We provide a scientific environment that is flexible, respectful and collaborative to our participants, researchers and all those we work with.
 - **Curious** – We search for new discoveries that can improve human health and quality of life. This is what motivates us.
 - **Changing** - We are constantly building knowledge that changes people’s lives.
3. The Raine Study resources will be managed in line with the agreed mission and values to optimise their utilisation and value for research and public benefit.
4. All researchers must abide by the [Australian Code for the Responsible Conduct of Research](#) when using the 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.
5. The Raine Study reserves the right to refuse a researcher’s access to the 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.
6. Projects conducted using the Raine Study resources must be [bona fide research](#). 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
7. Commercial research use of the Raine Study resources may be considered on a case-by-case basis, and involve discussion with and review by the Raine Study Directors, Scientific Review Committee and final approval following review by the UJV Board.
8. All projects conducted using the Raine Study resources must be compatible with the mission and values of the Raine Study.
9. Where possible, projects should involve collaboration with an existing member of a Raine Study Special Interest Group who is employed at one of the Raine Study financial partner organisations.



10. Where possible, projects should facilitate building research capacity in Western Australia.
11. Prior to commencement all research projects must have:
 - a. approval from the Raine Study; and
 - b. ethics approval.

2. Project Application Review and Approval Principles

2.1 General project applications

1. The detailed processes for applying for approval to conduct a project using the Raine Study resources are outlined on [the Raine Study website](#).
2. Templates for information required for project applications in the Raine Online Submission System (ROSS) are provided on [the Raine Study website](#). These templates are ideal for emailing between collaborators when preparing a project – although the final submission needs to be entered directly into ROSS.

2.2 All researchers planning a project

1. Researchers must normally be employed at a recognised research organisation with clear governance and commitment to conducting bona 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 throughout a project, including at an early stage in project planning. [The Raine Study team](#) will facilitate this.
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 team](#) 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 what they bring to the study (e.g. expertise, intellectual contribution).
8. The research team listed should include all those contributing intellectually to the research project including statisticians. Inclusion as a named team member does not necessarily imply 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 specific 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. However in this 2-5 year period, any such involvement is at the discretion of those initiating the project.

10. All contracts involving the 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 Grant and fellowship applications

1. Projects must have provisional approval from the Scientific Review Committee prior to grant applications being submitted to funding agencies.
2. All grant/fellowship applications need to include requests to support data access and ongoing curation of the Raine Study resources. This is currently set at 10% of the total grant value, to a maximum curation and access fee of \$100,000, for researchers employed by a UJV financial partner organisation or institutional associate member organisation and where the grant is administered by a UJV financial partner organisation. For researchers employed by other organisations or grants administered by other organisations a curation and access fee is currently set at 20% of the total grant value, to a maximum fee of \$200,000. 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 the Raine Study curation and access fees may be reduced in proportion to the contribution to the overall study. Any potential reduction in the 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 financial partner researchers and to capacity building in Western Australia.
4. All grant/fellowship applications should cover the total cost of research projects, including any data or biosample retrieval or collection and biosample analysis.
5. Grant/fellowship funded projects can only be commenced once all final protocols, budgets, resources and ethics approvals have been obtained and approved by the Raine Study.
6. For fellowship applications where the scheme either provides no project costs or small amounts of project costs, no curation and access fee will be set for projects lead by UJV financial partner or institutional associate member researchers. For projects lead by researchers from other organisations, an amount will be negotiated based on the financial capacity of the award. In most cases the Raine Study would expect a minimum contribution of \$15,000 for a 'standard' phenotypic data set and \$30,000 for a genetic data set.

2.4 Projects lead by researchers based at a UJV financial partner organisation or institutional associate member 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 at no cost to researchers based at a UJV financial partner organisation. Very large or complex data requests can require unusually large time commitments by the Raine Study staff or

collaborators to prepare analytical datasets. In these cases a curation and access fee will be negotiated with researchers prior to project approval.

2.5 Projects lead by researchers based at other organisations

1. Projects can be led by researchers employed at organisations which are not UJV financial partners of the Raine Study.
2. Research projects lead by researchers from organisations which are not UJV financial partners of the Raine Study should include in the project team investigator(s) who are employed at a UJV financial partner organisation, and ideally include in the project team an investigator(s) who has previously participated in at least one Raine Study project (from application through to manuscript submission).
3. Research projects conducted in organisations which are not UJV financial partners of the Raine Study are required to pay for access to existing data and other Raine Study resources and curation 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 financial partner researchers and funding organisations to provide funds, and the value of the project to UJV financial partner researchers and to research capacity building in Western Australia. For grant/fellowship applications, please see item 2.3 for further details.
4. Researchers who have moved from a UJV financial partner organisation to another organisation may negotiate reduced project costs in consideration for prior contributions to the Raine Study resource development.

2.6 Student projects

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 financial partner organisation and ideally one investigator should 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 UJV financial partner organisation will not normally need to pay for access to existing data.
6. Students enrolled at an organisation which is not a UJV financial partner of the Raine Study will need to pay a curation and access fee to use existing data. The fee for accessing the Raine Study resources must be negotiated prior to project approval.

2.7 Projects only involving use of existing data

1. Full approval can be given by the Scientific Review Committee as long as all financial, data, or any other resources necessary for the project have been acquired.



2.8 *Projects involving use of existing biosamples*

1. Researchers must provide detailed information in the application on: biosamples required, curation history requirements, analysis laboratory credentials, analysis method efficiency, reliability and validity, and relative merit of utilising these finite resources.
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 biosample handling procedures and materials transfer agreements.

2.9 *Projects involving collection of new data from participants*

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

2.10 *Projects involving collection of new biosamples from participants*

1. Researchers must provide detailed information in the application on: biosample required, collection protocol requirements, analysis laboratory credentials and analysis method efficiency, reliability and validity.
2. Templates for information required for ROSS are provided on [the Raine Study website](#). These templates are ideal for emailing between collaborators when preparing a project – although the final submission needs to be entered directly into ROSS (see items 2.1 and 3.1 for details).
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 material transfer agreements for biosample collection and immediate processing.

3. Project Conduct Principles

3.1 *General project conduct*

1. All researchers should abide to the Raine Study procedures for project conduct and reporting. The detailed procedures for conducting a project using the Raine Study resources are on [the Raine Study website](#).
2. Projects can only commence once they have received **full approval** from the Scientific Review Committee and have all required ethics approvals.
3. Any changes to an approved project, such as a change in research team or project focus, must be approved by the Raine Study. The amendment process in ROSS must be used for application and approval of changes.

3.2 *Obtaining data*

1. Prior to gaining access to any data all researchers handling data for a project must agree to the terms and conditions. These include:
 - a. recognising that the 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, according to the Raine Study procedures for data handling;

- c. returning derived variables generated as part of the project in a timely manner, with variable descriptions and coding guide, according to the Raine Study procedures for data handling.
2. All data for use in projects must come directly from the Raine Study.
3. All data requests must be for an approved project.

3.2.1 Obtaining sensitive or potentially identifiable data

1. Prior to gaining access to particularly sensitive or potentially identifiable data (e.g. date of birth, addresses), researchers are required to provide a detailed Data Management Plan, according to the Raine Study procedures for data handling. The Data Management Plan will be reviewed and approved by the Scientific Management Committee. The Data Management Plan will include a detailed description of how the data will be used (e.g. who will be handling the data, what computer(s) the data will be stored on, what software will be used for analysis and where the analysis will be done) and how and when the sensitive or potentially identifiable data will be destroyed by the research team and derived variables returned to the Raine Study.

3.2.2 Obtaining preliminary data

1. Access to preliminary data will only be available in limited situations:
 - a. to a research group which provided substantial funding for the follow-up in question;
 - b. for presentation at a conference with a published abstract;
 - c. and is not to be used for publication of a peer-reviewed journal paper or full paper peer-reviewed conference.
2. In general, any data to be used for these purposes would be restricted, according to the Raine Study procedures for data handling.

3.3 Obtaining existing biosamples

1. Prior to gaining access to any biosamples all researchers handling biosamples 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, according to the Raine Study procedures for biosample handling;
 - c. returning derived variables generated as part of the project in a timely manner, with variable descriptions and coding guide, according to the Raine Study procedures for biosample handling;
 - d. returning any unused materials, according to the Raine Study procedures for biosample handling.
2. Prior to gaining access to any biosamples, all organisations who will handle the biosamples must sign a Material Transfer Agreement, according to the Raine Study procedures for biosample handling. [The Raine Study team](#) will coordinate all Material Transfer Agreements.
3. Prior to gaining access to any biosamples, researchers are required to provide a detailed Data Management Plan, according to the Raine Study procedures for biosample handling. The Data Management Plan will be reviewed and approved by the Scientific Management Committee.

4. All biosample requests must be linked to a provisionally approved project.

3.4 *New data and/or 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 and/or biosample collection and immediate processing.

3.5 *Open access data*

1. No data from the Raine Study can be made available in the public domain as the Raine Study is committed to a high level of confidentiality of the data in line with the informed consent provided by participants.
2. If required by peer-reviewed journals or funding agencies, researchers should work with [the Raine Study team](#) to provide a statement on the Raine Study's policy regarding data availability.

3.6 *Using data for consortia projects and meta-analysis*

1. The Raine Study encourages use of its data to support multi-cohort consortia and other meta-analyses. Only summary data, not individual level data, is to be used for these purposes. Exemptions may be made to this policy where researchers can demonstrate:
 - a. a clear benefit for sharing individual level data;
 - b. a clear Data Management Plan detailing data security; and
 - c. evidence that the sharing of such data would not contravene any relevant regulations.

4. **Project Reporting Principles**

4.1 *General project reporting*

1. All researchers should abide to the Raine Study procedures for project conduct and reporting. The detailed procedures for reporting on a project using the Raine Study resources are outlined on [the Raine Study website](#).
2. All project investigators must abide by authorship standards as outlined in the [Australian Code for the Responsible Conduct of Research](#) and the supporting [Authorship guide](#), as well as where appropriate the [International Committee of Medical Journals Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals](#). These include:
 - a. reporting with respect for participants and to maintain confidentiality;
 - b. ensuring findings are reported fairly, accurately and fully;
 - c. appropriately citing prior publications and the work of others;
 - d. promoting scientific impact; and
 - e. promoting translation to practice and policy and public awareness.
3. Authorship is based on the following criteria:
 - a. "agrees to be listed as an author", and
 - b. "has made a significant intellectual or scholarly contribution to research and its output", which should include two or more of the following:
 - i. conception and design of the project or output;

- ii. acquisition of research data where the acquisition has required significant intellectual judgement, planning, design, or input;
- iii. contribution of knowledge, where justified, including Indigenous knowledge;
- iv. analysis or interpretation of research data;
- v. drafting significant parts of the research output or critically revising it so as to contribute to its interpretation.

4.2 Manuscript proposal 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 be related to 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, along with 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, appropriate nomenclature, and acknowledgements.
4. Manuscripts should use appropriate nomenclature and acknowledgements. These are provided on [the Raine Study website](#).
5. All MS approvals must be related to 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](#). These templates are ideal for emailing between collaborators when preparing a project – although the final submission needs to be via ROSS.

4.3 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 the Raine Study cohort, accurate, and in line with the mission and values of the Raine Study. Approval from the Raine Study must be obtained prior to any media release (MR).
4. MR approvals should be related to an approved project.
5. Researchers should liaise with [the Raine Study team](#) to enable prompt review and approval of media releases.

4.4 Presentations using the Raine Study resources

1. Researchers are required to maintain a record of all presentations (scientific conference, professional seminar, community talk) using the Raine Study resources and relevant research, and provide a summary to [the Raine Study team](#) for reporting purposes.
2. All presentations using the Raine Study resources should be related to approved projects.

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3. Use of a template for Raine Study slides is encouraged. Presentation templates are available [by request](#).

5. Scientific Management Committee review of project applications

- Scientific Management Committee members will conduct a preliminary review of new project applications and work with researchers to facilitate Scientific Review Committee review of projects.

6. Scientific Review Committee review of project applications

- Scientific Review Committee members must declare any potential conflicts of interest with project proposals.
- Scientific Review Committee members will not contribute to decisions on projects with which they have a potential conflict of interest.
- Project applications 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.
- The membership of the Scientific Review Committee will be regularly reviewed by the Raine Study Directors, with consideration to adequate representation of diverse expertise and partner organisations and capacity building.

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One of us
could change your life