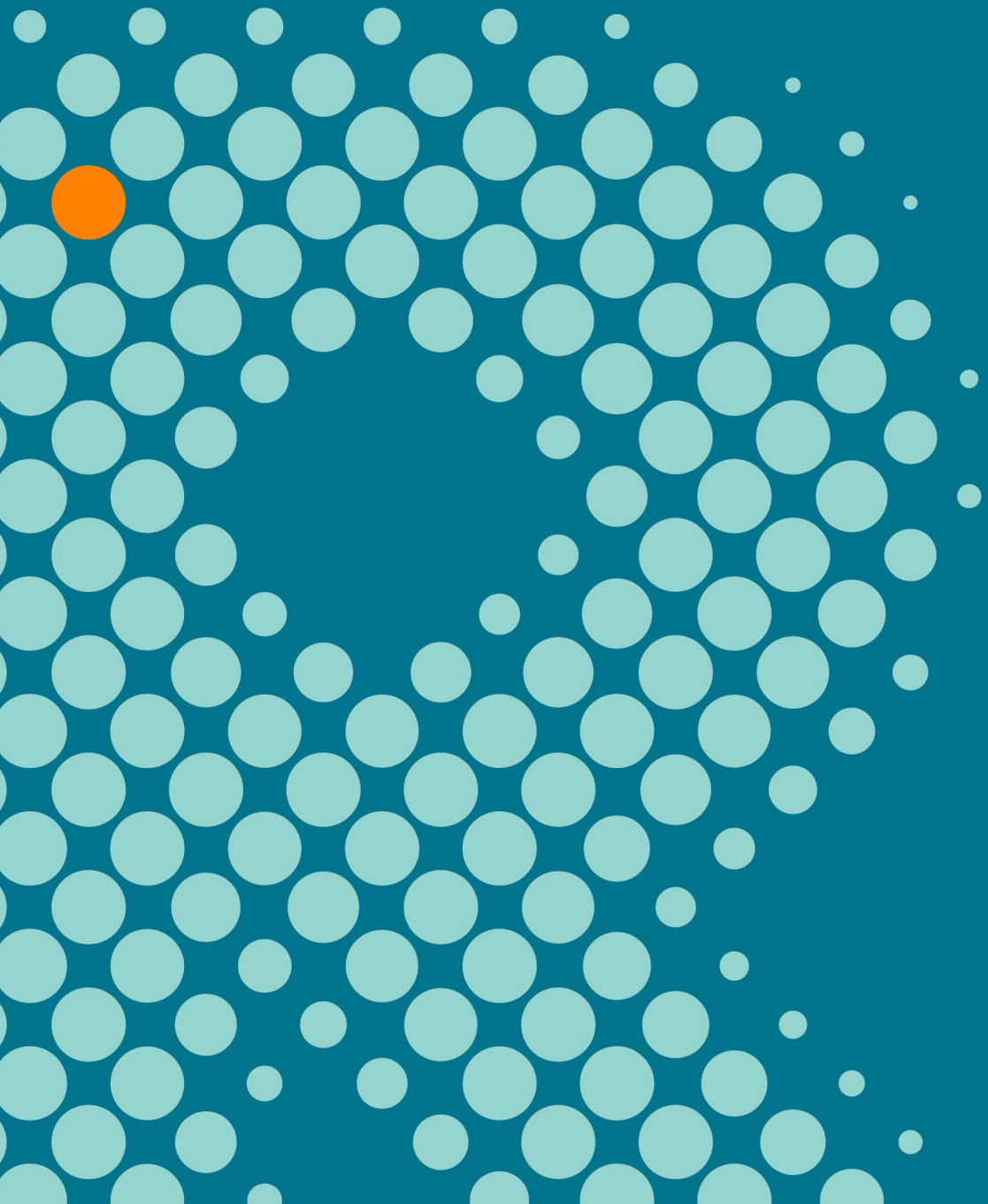
Researcher Engagement Policy
The Raine Study
(Version 6.2 - Revised by the Scientific Director)



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 600 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 owned and governed by an Unincorporated Joint Venture (UJV) partnership between the University of Western Australia (Group 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 Raine Study is the custodian of the data collected, and data is managed in accordance with the University of Western Australia’s Information Privacy Policy and Guidelines. The University of Western Australia is Group Agent for the Raine Study. This means that any data created, captured, or processed by the Raine Study is University information, and therefore subject to the University of Western Australia Information Governance Policies (https://www.uwa.edu.au/policy/home), which includes the University’s Information Privacy Policy and the University’s Information Protection Policy.

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. Salaried employees of UJV financial partners or individuals receiving funding that is administered through an UJV financial partner (referred to as “employed by” throughout the document) are eligible to receive the benefits outlined in the UJV agreement, including accessing Raine Study data at a reduced cost.
5. “Institutional Associate member” refers to non-UJV partner organisations formally approved as financial contributors to the Raine Study. Salaried employees of an Institutional Associate Member organisation or individuals receiving funding that is administered through an Institutional Associate member organisation are eligible to receive the benefits outlined in the UJV agreement, including accessing Raine Study data at a reduced cost.
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 a de-identified 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 biosamples 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. “Lead Investigator” is the researcher appointed to the ROSS project application and is responsible for the governance, oversight of analyses, publications and overall project conduct.
15. “Cohort Consultation” represents active engagement / partnership between the cohort participants and the researchers, ensuring the decision making, and shaping of the project includes input by the broader cohort community.

16. “Unfunded Projects” refers to research projects/proposals, submitted in ROSS, not related to grant/fellowship/funding applications.
17. “Policy” refers to this Researcher Engagement Policy.

This policy will be effective from December 2023 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 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 7
   - 2.1 General project applications 7
   - 2.2 All researchers planning a project 7
   - 2.3 Projects not related to a grant application and led by researchers employed by a UJV financial partner or institutional associate member organisation. 9
   - 2.4 Projects led by researchers employed by a non-UJV financial partner or institutional associate member organisation. 9
   - 2.5 Grant and fellowship applications 10
   - 2.6 Commercially funded research 11
   - 2.7 Projects not related to a grant/fellowship application (unfunded projects) 11
   - 2.8 Student projects 11
   - 2.9 Projects involving use of existing data 12
   - 2.10 Projects involving use of existing biosamples 12
   - 2.11 Projects involving collection of new data and / or new biosamples 13
3. Project Conduct Principles 13
   - 3.1 General project conduct 13
   - 3.2 Ethics committee approval for projects using existing Raine Study data and/or biosamples 13
   - 3.3 Ethics committee approval for projects proposing collection of new data and/or biosamples 14
   - 3.4 Obtaining data 14
   - 3.5 Obtaining sensitive or potentially identifiable data 15
   - 3.6 Obtaining preliminary data 15
   - 3.7 Obtaining existing biosamples 15
   - 3.8 Open access data 16
   - 3.9 Using data for consortia projects and meta-analysis 16
4. Project Reporting Principles 17
   - 4.1 General project reporting 17
   - 4.2 Manuscript submission approval 17
   - 4.3 Media related to findings from an approved project 17
   - 4.4 Presentations related to findings from an approved project 18
5. Scientific Management Committee review of project applications 19
6. Scientific Review Committee review of project applications 19

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:
   a. **Committed** – We are committed to innovation, discovery, and scientific rigour. Our staff, researchers and participants do what they do for the greater good.
   b. **Collaborative** – We provide a scientific environment that is flexible, respectful, and collaborative to our participants, researchers and all those we work with.
   c. **Curious** – We search for new discoveries that can improve human health and quality of life. This is what motivates us.
   d. **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. treating fellow researchers and Raine Study staff fairly and respectfully;
   e. respecting participants; and
   f. respecting the community at large.
5. The University of Western Australia is the employer of all Raine Study staff and the Centre Agent for the Raine Study, which includes its participants. As noted in the UWA Code of Ethics and Code of Conduct (Policy Number UP07/6), the University seeks to provide a Campus culture marked by mutual respect, personal dignity and support for everyone's skills and abilities, where Employees and Students may reasonably expect to pursue their work in a safe and civil environment free from discrimination, harassment, threatening or violent conduct or offences against individuals or property. In particular, the University will not tolerate bullying or harassment including disability, racial, or sexual harassment. In line with this Code, inappropriate behaviour and/or lack of respect by Raine Study researchers towards Raine Study staff or participants will not be tolerated by the University.
6. 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, the UWA Code of ethics and Code of Conduct or the Australian Code for the Responsible Conduct of Research in relation to the Raine Study.
7. 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;
8. The Raine Study supports all ethically justified and scientifically sound research, as reviewed by the Raine Study Scientific Review Committee and an approved Ethics committee.

In situations where projects have a potential degree of overlap or similarity to existing projects, the Raine Study may recommend that the researcher contact researcher(s) working in similar areas to advise them of their project and invite them to collaborate on the project. The Raine Study is not responsible for ensuring there is no overlap or duplication of research projects.

a) Exceptions to the above may be considered for PhD student projects which are yet to submit and/or publish findings.
b) Where a researcher has financially enabled collection of data and/or analysed the data as part of a grant / fellowship, after the initial exclusivity period finishes (usually 2 years after final data collection and researcher receipt of data), the data must be returned to the Raine Study and be made available to other researchers.

9. Projects funded in part or in whole by a commercial entity 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.
10. All projects conducted using the Raine Study data and/or biosamples must be compatible with the mission and values of the Raine Study.
11. Where possible, projects should involve collaboration with an existing member of a Special Interest Group from the Raine Study who is employed at one of the Raine Study financial partner organisations.
12. Where possible, projects should facilitate building research capacity in Western Australia.
13. The Raine Study staff involvement as a co-investigator in a research project does not imply Raine Study approval.
14. Prior to commencement of a research project, the research team must have:
    a. Final approval from the Raine Study via the Raine (Study) Online Submission System (ROSS); and
    b. Worked with the Scientific Management team to ensure feasibility and acceptability of project, including finances, data and/or biosamples collection and nalyses protocols, participant burden, and ethics committee approval (see Appendix Figure 1).

2. Project Application Review and Approval Principles

2.1 General project applications

1. The detailed process 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 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. The position of the Lead Investigator is not a nominal position. The researcher appointed as the lead investigator on a project is responsible for the overall project, including governance, oversight of analysis and write up of publications.
3. Existing projects are not transferrable to a different lead investigator, unless that lead investigator officially accepts and assumes full responsibility for all aspects of the project.
4. Researchers must declare any potential conflicts of interest in any project.
5. 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.
6. It is expected that researchers set up cohort consultation and involve participant representatives to help develop the project proposal in the early planning stages. This ensures that research decisions are guided by suggestions from the broader community about what research they consider useful and relevant.
   There are three levels of effective cohort consultation facilitated by the Raine Study staff:
   a. Focus group - A group of participants are recruited from the cohort (Gen1 and/or Gen2) and provided with a plain language summary and presentation of the research proposal in a meeting setting. The focus group members provide feedback through a discussion with the researcher at the meeting.
   b. Research Buddy – A self-identified cohort member/s (Gen1and/or Gen2) that regularly meet with researchers during the planning and design phase of a project. The Research Buddy can continue involvement with the research team throughout the life of the project. The Raine Study encourages the research team to include the research buddy as an Associate Investigator on the project proposal to the funding body.
   c. The Raine Study Community Advisory Committee (RSCAC) - is an executive body made up of Gen1 and Gen2 representatives. This committee advises on operational activities in the Raine Study. Projects may be briefly presented to this Committee, followed by general feedback from the members on the proposal (see Appendix, Figure 2).

   Depending on the scope of the consultation required, there may be associated costs which should be factored into project budgets. The Raine Study team will facilitate and advise on this when the initial request is made. Further information related to cohort consultation for grant / fellowship applications can be found in point 9 under subheading 2.5.

7. Researchers must consider how the resources needed to conduct any project in a timely manner can be acquired. These resources include personnel, equipment, and funding related to data and/or biosamples curation and access or to collection of new data and/or biosamples, as relevant. Researchers must discuss and agree on these resources with the Raine Study Scientific Management team prior to the submission of any project application. This includes applications to funding agencies.
8. Researchers must meet with the Raine Study staff to discuss fees related to data access, collection, curation and/or cohort consultation. Please see Appendix, Figure 3. for estimated data curation and access fees.
9. Budgets must clearly show what funding will be managed by the Raine Study team and what will be managed by the project research team.
10. All necessary resources need to be in place before final approval to start a project will be provided.
11. 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). 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).
12. Researchers who have contributed substantially to the acquisition of data and/or biosamples will have priority access to those specific resources for two years after the data and/or biosamples 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 data and/or biosamples. However, in this 2–5-year period, any such involvement is at the discretion of those initiating the project.
13. If data used in previously approved, unpaid projects become the subject of a subsequent grant application, a contribution towards data access fees will apply as per the data fee schedule for grant/fellowship applications (please see item 2.5 for further details and Appendix Figure 3).
14. Project applications in ROSS will have to be specific and with defined timelines. Researchers must include a start and finish date in their ROSS application. Project approval is normally for a period of 3 years. Researchers can request an extension to the project approval at the end of that 3-year period, which may attract additional fees. In the case where a grant is administered over 5 years, the project can be approved for a 5-year period.
15. Any amendments submitted after the completion date such as: additional aims broadening the scope of the project, proposed new data analyses and/or additional data requests will incur a fee that will be specific to the project and must be discussed with the Science and Data teams. This is applicable to researchers employed by both UJV affiliate and non-affiliate institutions.
16. All contracts involving the collection or analysis of Raine Study data and/or biosamples must be approved by the Raine Study and would normally be with the Raine Study directly, not the project research team.
17. UJV financial partner and institutional associate member benefits are available to:
    a. Individuals who are salaried by or receive funding that is administered through the UJV financial partner or associate member institution.
    b. Emeritus Professors from an UJV financial partner or associate member institution (with a grace period of five years).
    c. Researchers with Honorary positions at the Telethon Kids Institute.
    d. Clinical adjuncts from an UJV financial partner or associate member institution.

18. Benefits of becoming an associate member (formally approved financial contributors) to the Raine Study include:
    a. An agreed quota of project applications per year for the duration of the agreement between the associate member institution and the Raine Study.
    b. No data access fee for up to 1000 variables per project per year for the agreed period (excluding grant/fellowship applications).
    c. Discounted data access and curation fee for grant applications (10% instead of the 20% as applicable for external organisations; see Appendix Figure 3).

    Institutional Associate member benefits apply to the whole university, with, where relevant, the faculty who funded the agreement overseeing the governance of their institute's access and use. Please contact the Raine Study Directors and Operations Manager to discuss the details.

2.3 Projects not related to a grant application and led by researchers employed by a UJV financial partner or institutional associate member organisation.

1. If the project lead is new to the Raine Study, we recommend involving one or more researchers who have previously participated in at least one completed project in the Raine Study (i.e., from project application through to manuscript submission), in order to assist the project lead to navigate ROSS and the Raine Study's processes and data.
2. If the project is not related to a grant or funding application, access to existing data will normally be provided at no cost to researchers employed by a UJV financial partner or institutional associate member organisation, according to the conditions set within the agreement between the Raine Study and the 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 data and/or biosamples curation and access fee will be negotiated with researchers prior to project approval.

2.4 Projects led by researchers employed by a non-UJV financial partner or institutional associate member organisation.

1. Projects can be led by researchers employed by organisations which are not UJV financial partners or institutional associate members of the Raine Study. We recommend involving one or more researchers from one or more of the UJV financial partner organisations, and ideally one or more researchers who have previously participated in at least one completed project in the Raine Study, in order to assist the project lead to navigate ROSS and the Raine Study's processes and data.
2. Research projects led by researchers employed by organisations which are not UJV financial partners or institutional associate members of the Raine Study are required to pay for data and/or biosamples curation and access, as well as cover any additional costs either for new data and/or biosamples collection, or for existing biosamples' preparation, transport, and analysis. Costs must be negotiated with the Raine Study prior to project submission in ROSS 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 2.5 for further details.

3. 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 development.

2.5 Grant and fellowship applications

1. Projects must have provisional approval from the Raine Study prior to grant/fellowship applications being submitted to funding agencies.
2. For funding bodies requiring an EOI, a project application in ROSS is only required If the researcher successfully moves into the full grant/fellowship application stage.
3. A copy of the grant/fellowship application documents, including budget information, will need to be attached to the project application in ROSS. Access to this information will be restricted to the Scientific Management team. The Scientific Management team will ensure confidentiality and abide to the data management and security policies adopted by our central agent.
4. Changes to the project application, including budget information, that was provisionally approved by the Raine Study must be re-approved by the Scientific Management team before the grant is accepted.
5. Final approval from the Raine Study will be provided when the Scientific Management team has worked with the researchers to ensure the feasibility and acceptability of the planned access to existing data and/or biosamples, as well as collection of new data and/or biosamples. The Scientific Management team will consider aspects such as available finances (e.g., data and/or biosamples curation and access fess, other project costs), concurrent projects and participant burden. Further, the access to or collection of data and/or biosamples can only commence once all final protocols, budgets, resources, and ethics committee approval have been obtained and approved by the Raine Study.
6. If the same grant application is submitted to another funding body or is resubmitted following an unsuccessful outcome, a new project application must be submitted in ROSS. This new application in ROSS should incorporate revised details on the funding body/scheme, submission year, budget/funding distribution, expected start and completion date, grant file documents including the budget file and any changes made to research aims/methods from the original proposal.
7. All grant/fellowship applications should cover the total cost of research projects, including any data and/or biosamples retrieval or collection, and biosamples preparation, transport and analysis.
8. All grant/fellowship applications need to include requests to support data access and ongoing curation of the Raine Study resources (see Appendix Figure 3). This is currently set at:
    a. 10% of the total grant/fellowship value, to a maximum data curation and access fee of $100,000 p/a for researchers employed by and where the grant is administered by a UJV financial partner organisation or institutional associate member organisation.
    b. 20% of the total grant/fellowship value, to a maximum data curation and access fee of $200,000p/a for researchers employed by and where the grant is administered by other organisations.
    c. Grants with total value lower than $25,000 can use a reduced rate of 5% and grants with total value lower than $50,000 can use a reduced rate of 10%.
9. Where the Raine Study resources represent only a part of a larger study, then the Raine Study data curation and access fees may be reduced in proportion to the contribution to the overall study. Any potential reduction in the Raine Study's data curation and access fees must be negotiated before provisional and/or final 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.

10. 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 led by researchers employed by an UJV financial partner or institutional associate member organisation. For projects led by researchers from other organisations, an amount will be negotiated based on the financial capacity of the award.
11. A degree of cohort consultation is routine as part of the project application process. Participants are active members in governance committees (Operations Management Committee, Scientific Review Committee and the Raine Study UJV Board), consequently ensuring research decisions are guided by suggestions from the broader community about what research they consider useful and relevant. This level of cohort consultation is provided in-kind; thus, it should be included in relevant sections (background, methodology, ethics application) of the grant application document to the funding body.
    Certain projects may require more specific cohort consultation such as focus groups, participant representatives, Research Buddies, workshops, brief presentation at the RSCAC meeting and ultimately including participants as associate investigators. (see Appendix Figure 2). Selecting the type of consumer involvement is imperative for accurate cost calculation, and the fee should be included in the budget for the grant proposal. Please liaise with the Raine Study team for details on additional information regarding the process for cohort consultation and the associated cost.

2.6 Commercially funded research

1. Projects funded in part or in whole by a commercial entity can be undertaken as long as ethical, scientific, reputational and legal arrangements are adequate.
2. Industry data and/or biosamples curation and access fees must be arranged by negotiation with the Scientific Management team, before being presented to the Raine Study UJV Board.
3. Final approval for any commercially funded project will be provided by the Raine Study UJV Board following usual project application review and approval principles described previously. The Raine Study UJV Board will review such projects on a case-by-case basis.
4. Existing summary-level Raine Study data may be shared with a commercial partner and does not present any privacy issues, if approved by the Raine Study UJV Board.
5. Existing de-identified individual-level Raine Study data may be shared with a commercial partner if approved by The Raine Study UJV Board, which should follow the recommendations of the University of Western Australia (UWA) Risk Management and Legal teams. Such a decision would be based primarily on the magnitude of any risk posed to the organisation (and the Raine Study) if the project were to proceed.

2.7 Projects not related to a grant/fellowship application (unfunded projects)

For projects not related to grant/fellowship, the Raine Study would expect a minimum contribution of $15,000+GST for a ‘standard’ phenotypic data set and $30,000+GST for a genetic data set (see Appendix Figure 3).

2.8 Student projects

1. Student projects should be submitted as a separate project for approval in ROSS.
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 (primary) supervisor. The main supervisor is responsible for the governance, oversight of analyses,

publications and overall project conduct.

4. If more than one student is involved with a particular project addressing the research questions/aims, a detailed data management plan (DMP) which limits the data access to the specific research project should be prepared and signed by the Data and Biosamples Manager before the data can be released. The main supervisor is responsible for adherence to the agreed DMP. All students should be included as data handlers on the data request form.
5. As with other projects, we recommend involving one or more researchers from one or more of the UJV financial partner organisation and ideally one or more researchers who have previously participated in at least one completed project in the Raine Study project, in order to assist the project lead to navigate ROSS and the Raine Study's processes and data.
6. As with projects led by researchers affiliated with an UJV financial partner or institutional associate member organisation, students enrolled at one of these organisations will not normally need to pay for access to existing data, according to the conditions set within the agreement between the Raine Study and the organisation. When very large or complex data requests are involved, a data and/or biosamples curation and access fee will be negotiated with researchers prior to project approval (see Appendix Figure 3).
7. As with projects led by researchers affiliated with organisations which are not UJV financial partners or institutional associate members of the Raine Study, students enrolled at one of these organisations will be required to pay a data and/or biosamples curation and access fee (see Appendix Figure 3), as well as cover any additional costs either for new data and/or biosamples collection, or for existing biosamples' preparation, transport and analysis. Costs will be negotiated prior to project submission in ROSS.

2.9 Projects involving use of existing data

Final approval will be provided by the Raine Study once the Scientific Management team has worked with the researchers to ensure the feasibility and acceptability of the planned access to existing data. Access to data will only be provided following payment of the data curation and access fee (see Apendix Figure 3) and ethics committee approval has been obtained and approved by the Raine Study.

2.10 Projects involving use of existing biosamples

1. Researchers must provide detailed information in the project application and biosamples request in ROSS on: biosamples required, curation history requirements, analysis laboratory credentials, analysis method efficiency, reliability and validity, relative merit of utilising these finite resources and funding needed for biosamples preparation, transport, and analysis.
2. Provisional approval can be given by the Raine Study to enable the research project team to work with the Scientific Management team to finalise biosamples handling procedures and materials transfer agreements.
3. Accessing the biosamples incurs a fee that must be discussed with the Raine Study Team. It factors in the finite nature of the resource, and it is project specific.
4. Final approval will be provided by the Raine Study once the Scientific Management team has worked with the researchers to ensure the feasibility and acceptability of the planned access to existing biosamples, and ethics committee approval has been obtained and approved by the Raine Study.

2.11 Projects involving collection of new data and / or new biosamples

1. Provisional approval can be given by the Raine Study to enable the research project team to work with the Scientific Management team to finalise protocols related to new data and / or new biosamples collection including material transfer agreements for biosamples' collection, storage and processing.
2. The research team should liaise with the Follow-up Coordinator and the Operations Manager to discuss the cost associated with the collection of new data and/or biosamples. The researchers are expected to provide the information around the processes, procedures and technical equipment needed for the data collection they require in the project application in ROSS. Additional costs may apply such as the need for cohort consultation, staffing and miscellaneous costs that are project specific.
3. Final approval will be provided by the Raine Study once the Scientific Management team has worked with the researchers to ensure the feasibility and acceptability of the planned data collection, and ethics committee approval has been obtained and approved by the Raine Study.

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 data and/or biosamples are on the Raine Study website.
2. Projects can only commence once they have received final approval by the Raine Study and ethics committee approval has been obtained and approved by the Raine Study.
3. Any changes to an either provisionally or finally approved project, such as a change in budget, research team or project focus, must be approved by the Raine Study. The amendment process in ROSS must be used for submission and approval of changes.

3.2 Ethics committee approval for projects using existing Raine Study data and/or biosamples

1. The UWA Human Research Ethics Committee (HREC) provided the Raine Study with a single consolidated approval (RA/4/20/5722) for use of the Raine Study existing data and/or biosamples.
2. Once a project receives provisional or final approval by the Raine Study, the lead researcher needs to seek project approval from an HREC. A researcher can only submit a project to an HREC after it has been provisionally or finally approved by the Raine Study. Usually, the project will be submitted to the HREC (Institutional Review Board,
   or equivalent) at the lead researcher's employing institution (both nationally and internationally) on condition that the project goes through an appropriate review process. Evidence of the process and approval should be provided to the Raine Study. For Australia, this would be by an NHMRC registered HREC. The lead researcher may use the Raine Study provisional or final project approval (recorded in ROSS) and the single consolidated UWA HREC approval for use of the Raine Study existing data and/or biosamples to support the submission of the project to their HREC. The lead researcher is responsible for providing a copy of the final HREC approval from their institutional HREC (Institutional Review Board, or equivalent) to the Raine Study before gaining access to any data and/or biosamples.

3. Based on the National Statement (NS 3.1.62), all projects need to receive approval from an HREC, and researchers need to approach their HREC to determine the specific submission processes required of them. It is possible that use of the existing data and/or biosamples held by the Raine Study will be considered low risk from an ethical perspective given that their proposed study will already have undergone robust internal scientific review by the Raine Study and be accompanied by the single consolidated WA HREC approval for use of previously collected data and/or biosamples. However, research using the Raine Study data and/or biosamples may qualify as high risk even though it is using existing data, and thus need a new, full HREC review. For an indication of research requiring full HREC review refer to the National Statement (NS 5.1.6)

3.3 Ethics committee approval for projects proposing collection of new data and/or biosamples

1. Any project proposing to collect new data and/or biosamples from the Raine Study's participants is required to have final approval from the Raine Study and approval from an HREC (Institutional Review Board, or equivalent) before any data collection can take place.
2. Usually, a project involving collection of any new data and/or biosamples will also seek to utilise the historical, longitudinal data that have been collected. In their submission to an HREC, researchers may refer to the single consolidated UWA HREC approval (RA/4/20/5722) which provides ethical compliance for use of the Raine Study existing data and/or biosamples.

3.4 Obtaining data

1. Prior to gaining access to data, any researcher who will handle data for an approved project must be allocated 'data handler' status. This is done as part of the data access request in ROSS and confirmation of involvement as a data handler means that the researcher agrees to the terms and conditions of data access. 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 a project that has received final approval by the Raine Study.
4. Once data handlers have downloaded the data, they are responsible for maintaining data security and confidentiality in line with ethics committee protocols. If data needs to be shared between data handlers (within or across organisations), secure data transfer protocols are required[1]. Data cannot be shared with any other individuals (even in the same research team) unless they have been allocated data handler status by the Raine Study through ROSS.
5. The lead researcher for an approved project has the responsibility to retain clear, accurate, secure and complete records of all research including research data and primary materials according to the Australian Code for the Responsible Conduct of Research and the project ethics committee approval.
6. The lead researcher for an approved project has the responsibility to return all derived variables[2] generated as part of the project, with variable descriptions and coding guides, in a timely manner. The Raine Study will keep record of the data accessed by researchers and any derived data returned from an approved project.

3.5 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 using the Raine Study template provided, according to the Raine Study procedures for data handling. The Data Management Plan will be reviewed and approved by the Scientific Management team. The Data Management Plan will include a detailed description of why such data are required, 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 derived variables will be returned to the Raine Study.

3.6 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.

3.7 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 biosamples 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 biosamples handling.
    d. returning any unused materials, according to the Raine Study procedures for biosamples handling.
2. Prior to gaining access to any biosamples, all organisations who will handle the biosamples must sign a Material Transfer Agreement3, according to the Raine Study procedures for biosamples handling. The Scientific Management team will coordinate all Material Transfer Agreements, which require legal review.
3. Prior to gaining access to any biosamples, researchers are required to provide a detailed Data Management Plan, using the Raine Study template, according to the Raine Study procedures for biosamples handling. The Data Management Plan will be reviewed and approved by the Scientific Management team.
4. All biosamples requests must be linked to a project that has received at minimum provisional approval.

[1] Please contact the Scientific Management team if you would like guidance on secure data transfer protocol

[2] Please discuss with the Scientific Management team which derived variables need to be returned to the Raine Study

3.8 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 Scientific Management team to provide a statement on the Raine Study's policy regarding data availability.

3.9 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 de-identified individual-level data, are to be used for these purposes. Exemptions may be made to this policy, pending the Raine Study final approval, where researchers can demonstrate:
    a. a clear benefit for sharing de-identified 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.
2. Where a consortium project is led by a researcher/s employed by a UJV financial partner organisation or an associate member organisation, access to the summary data will be provided at no cost if the project is not subject of a grant. If the consortia are conducting multiple projects, each project must be submitted in ROSS and will be counted as a separate project under their agreement with the Raine Study.
3. Access to summary data where the researchers are employed by non-UJV financial partner organisation or an associate member organisation will incur a minimum $6,000 fee in line with the data access fee schedule (see Appendix Figure 3). The final fee will be discussed with Raine Study staff and will be dependent upon the data request.

[3] Please contact the Scientific Management team to initiate the preparation of the Material Transfer Agreement.

4. Project Reporting Principles

4.1 General project reporting

1. All researchers should abide by 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 researchers 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 studies with respect for participants whilst maintaining 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 to contribute to its interpretation.

4.2 Manuscript submission approval

1. Approval from the Raine Study must be obtained prior to submitting a manuscript to a journal, via a Manuscript Submission (MS) in ROSS. A copy of the manuscript ready for submission is required as part of the MS. Manuscripts will be checked for similarity/plagiarism, potential negative impact on the cohort, appropriate nomenclature, and acknowledgements.
2. Appropriate nomenclature and acknowledgements should be used in all manuscripts. The Raine Study Nomenclature and Acknowledgement Guidelines can be found in our website.
3. All MS approvals must be related to an approved project.
4. A template with the information required as part of the MS in ROSS is provided on the Raine Study website. The template is ideal for emailing between collaborators when preparing a manuscript – although the final submission needs to be via ROSS.

4.3 Media related to findings from an approved project

1. Researchers are encouraged to promote translation of findings from an approved project 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 the paper is published).

3. Research findings must be discussed in the media in a manner that is sensitive to the Raine Study participants, accurate, and in line with the mission and values of the Raine Study
4. If you need assistance deciding how or whether to engage with media, please contact the press office at your organisation or funding body in the first instance. Once they have provided you with guidance relevant to your organisation, let them know that you also need to co-ordinate with the Raine Study Communications Manager to ensure appropriate inclusion of information about the Raine Study in the press release or media announcement, and prompt review/approval of the final press release or media announcement.
5. While not all findings from research projects will have a press release written about them, we encourage all Raine Study researchers to share details of their approved research findings via social media (Twitter, LinkedIn, Facebook or other). Before doing so:
    a. Ensure you have permission from the publisher to share links to publications, journals or research papers on social media;
    b. Ensure you acknowledge all relevant parties (e.g. co-authors, participants, funding partners, data sources);
    c. Tag the Raine Study – @TheRaineStudy (Facebook), @rainestudy (LinkedIn) or @rainestudy (Twitter). This way, we can also help share your work.
    d. Reach audiences beyond your own personal networks by tagging your organisation's official social media pages, your colleagues and peers.
6. Further details about correct use of the Raine Study brand, logo and "About the Raine Study" information can be found at the Raine Study website.

4.4 Presentations related to findings from an approved project

1. All presentations using the Raine Study data and/or biosamples should be related only to projects that have received final approval.
2. Researchers are required to maintain a record of all presentations (e.g. scientific conference, professional seminar, community talk) using the Raine Study data and/or biosamples and relevant research, and provide a summary to the Raine Study team for reporting purposes.
3. Appropriate nomenclature and acknowledgements should be used in all presentations. The Raine Study Nomenclature and Acknowledgement Guidelines can be found in our website.
4. Use of a template for Raine Study slides is encouraged, including logos from our UJV financial partners. Presentation templates and logos are available by request.

5. Scientific Management Committee review of project applications

1. Scientific Management Committee members will conduct a preliminary review of new project applications and work with researchers to facilitate Scientific Review Committee review and costs of projects.
2. Scientific Management Committee members must declare any potential conflicts of interest with project proposals.
3. Scientific Management Committee members will not contribute to decisions on projects with which they have a potential conflict of interest.

6. Scientific Review Committee review of project applications

1. Scientific Review Committee members will conduct a full scientific review of new project applications and provide recommendations for amendments and/or approval.
2. Scientific Review Committee members must declare any potential conflicts of interest with project proposals.
3. Scientific Review Committee members will not contribute to decisions on projects with which they have a potential conflict of interest.
4. Project applications will be reviewed for scientific rigor, likely importance of findings, expertise of research team, feasibility, and impact on participants.
5. Where insufficient expertise exists within the Scientific Review Committee, independent scientific reviews will be obtained.
6. The membership of the Scientific Review Committee will be regularly reviewed by the Raine Study Directors, with consideration to adequate representation from individuals with diverse expertise, from across partner organisations, and with a view to capacity building.

Appendices:

Figure1: Project Review and Approval

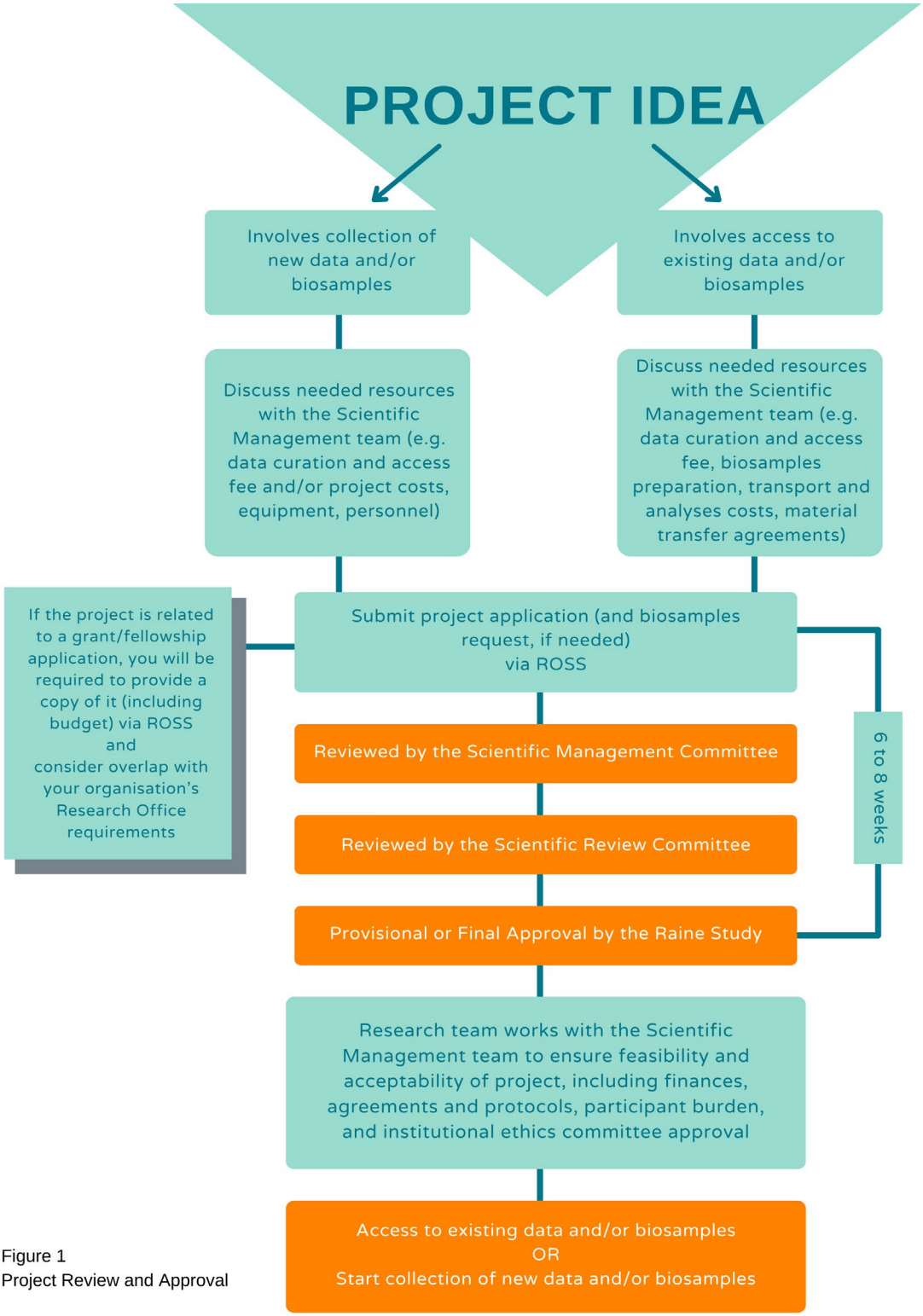


Figure 1
Project Review and Approval

Figure 2. The Raine Study Cohort Consultation options

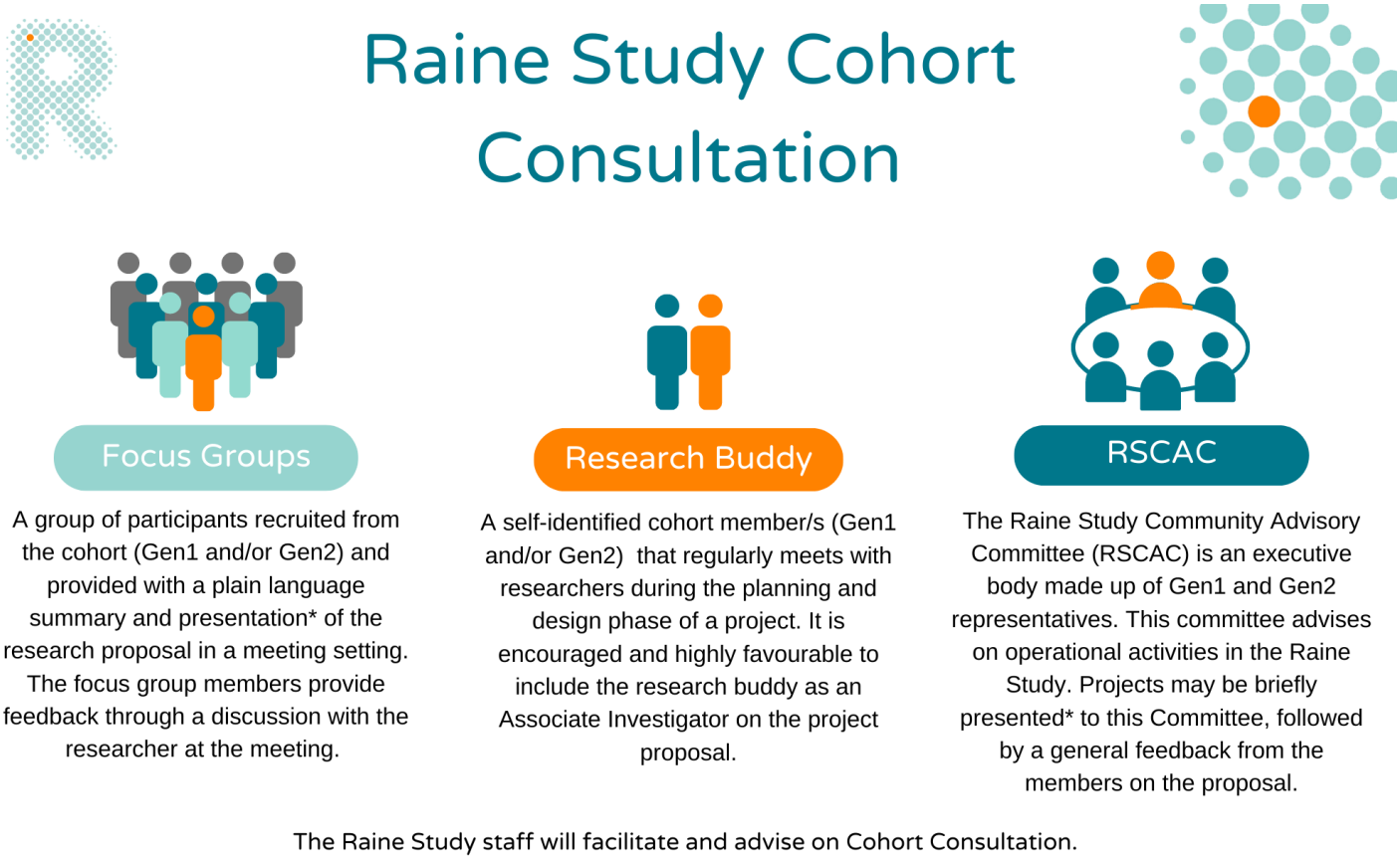
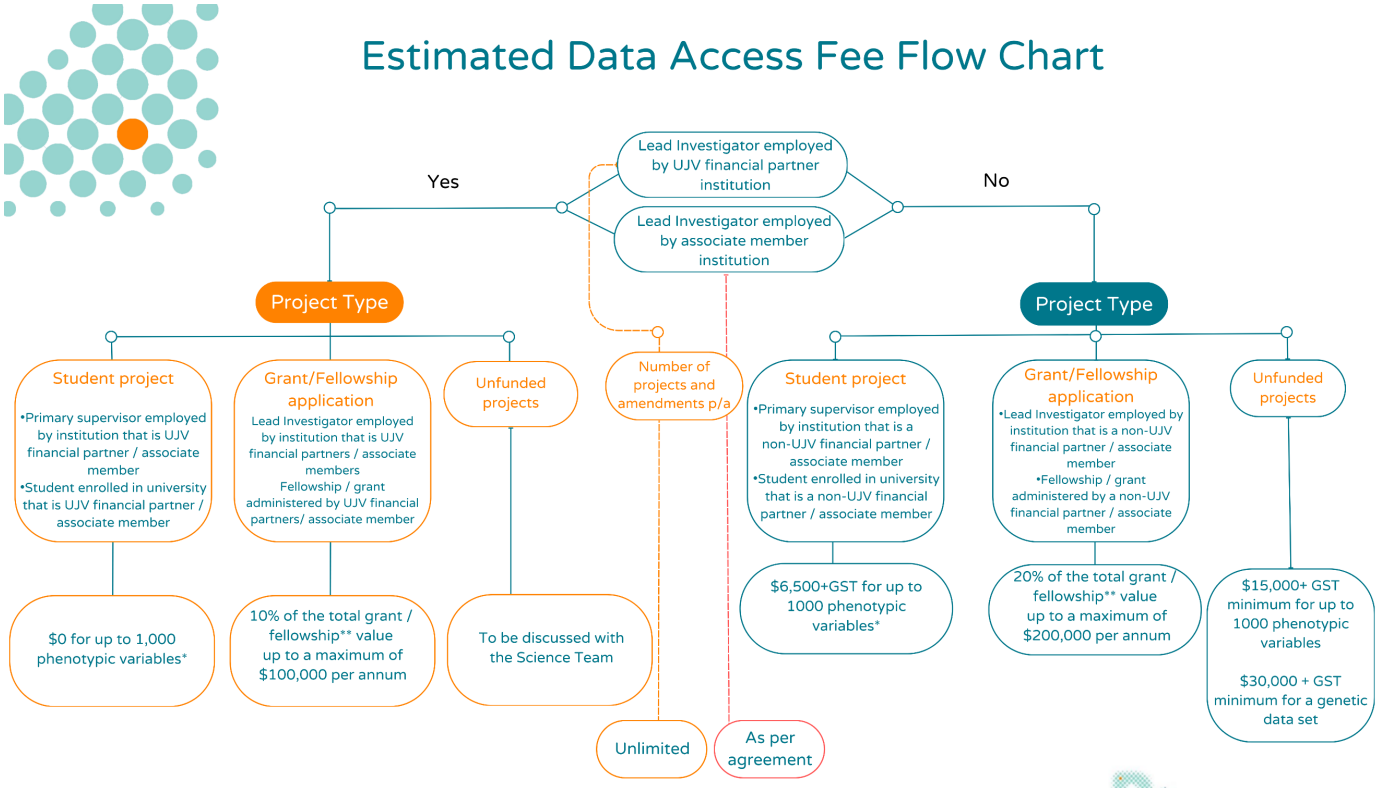


Figure 3. Estimated Data Access and curation fee flow chart



* For very large or complex data requests, a more appropriate fee will be discussed with the student researcher prior to project approval.
Genetic variables are counted as 1 variable towards the 1,000 provided. Analyses are performed using Pawsey.
** Grants with total value lower than $25,000 can use a reduced rate of 5%
** Grants with total value lower than $50,000 can use a reduced rate of 10%.
Access to summary data for consortia projects where the researchers are employed by a non-UJV financial partner organisations incur a minimum fee of $6,000.
Amendments to projects introducing additional aims/analyses necessitating review by the SRC will incur a fee of $500.
All data and curation fees must be discussed with the Data and Science Teams. All fees are in Australian Dollars.