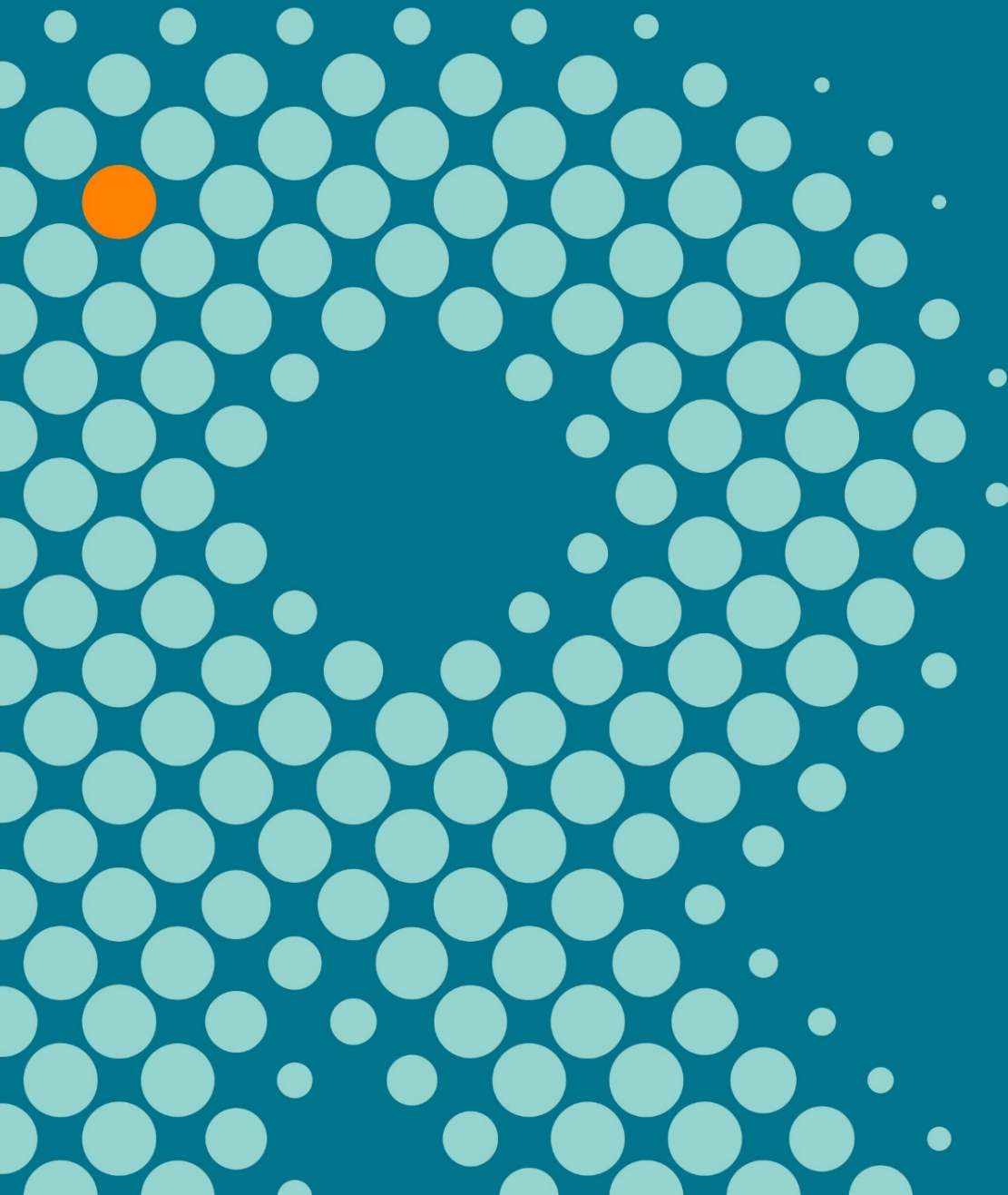


# GRANT AND FELLOWSHIP APPLICATION INFORMATION

The Raine Study





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## General information

Grant applications based on the use of previously collected Raine Study data are encouraged. Such studies have fewer implications on the Raine Study participants, staff and logistics, therefore there are less restrictions on these applications.

Grant applications based on collection of new data on the Raine Study participants (Gen0, Gen1, Gen2 or Gen3, or a combination of generations) need to consider the total cost of the cohort recall and data collection and the burden impact on the cohort. Funding a cohort follow-up typically requires a minimum of \$500K pa for 3 years. In the past it has been difficult for a single grant to fully cover the data collection costs of a follow-up, so often several grants have been pooled to enable data collection. Without sufficient funding a follow-up can not be initiated.

Grant applications for new data collection need to be discussed with the Raine Study Directors and Scientific Management Committee as early as possible to ensure it would fit in with other participant commitments and be able to meet necessary costs. Grant applicants involving new data collection are requested to include minimum data collection staff FTE requirements to cover a proportion of core cohort data collection (anthropometry, blood pressure, core socio-economic data) in addition to the FTE requirements to cover project specific data collection.

The following information is provided to ensure grant applications contain consistent information. Any investigator queries should be discussed with the Raine Study team.

Prior to submission, all grant applications should have provisional approval from the Raine Study Scientific Review Committee (after project application via the Raine Online Submission System - ROSS). All final grant applications including budget details need to be reviewed by the Scientific Management Meeting Committee prior to submission to grant authorities. Please note the usual process for a new project/grant application approval (i.e. Scientific Management Committee review then Scientific Review Committee Review) takes 6 to 8 weeks.

Investigators are encouraged to contact the Raine Study Scientific Officer (raineadmin-sph@uwa.edu.au) in the first instance with any queries regarding grant application preparation.

## For all grants

### *The Raine Study cohort curation and access fee*

A cohort curation and access fee must be included in all grants submitted by researchers wishing to utilise the Raine Study resources. 10% of the total grant value, to a maximum of \$100,000 for researchers employed by a UJV partner organisation and where the grant is administered by a UJV partner organisation, and 20% of the total grant value, to a maximum of \$200,000 for researchers employed by other organisations or grants administered by other organisations. 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%. For fellowship applications where the scheme either provides no project costs or small amounts of project costs, no fee will be set to projects lead by UJV partner 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. The curation and access fee may also be reduced where utilisation of the Raine Study data forms part of a multi-cohort grant application. Please discuss this with the Raine Study Scientific Management team.

### **The Raine Study cohort curation and access fee contributes to costs associated with:**

- Access to the Raine Study previously collected data and biological samples.
- The Raine Study governance and management activities including co-ordination of ethics applications, project and manuscript review and approvals and study protocol quality control.
- Project budgeting, cost management, and risk management.
- Integration of all research involved in the cohort follow-up.
- Questionnaire and database development.
- Study participant retention, including website, newsletters, and cards.
- Consumer consultation and participation.
- Curation of previously collected longitudinal Raine Study data, including phenotypic and genetic information.
- Curation of previously collected biological samples.
- Communication, website and newsletters.

### *The Raine Study cohort curation and access fee – suggested wording for grant applications*

*Cohort curation costs relate to the governance and maintenance of the cohort, curation of the existing data and biological samples, and overall project coordination and management of new data collection. This fee also covers the cost to access previously collected data. The Raine Study core management currently costs around \$600,000 p.a., which is funded by pooling the cohort curation and access fee included in all grants together with financial contributions from partner universities and research institutions. This fee has been set by the Raine Study at [\$100,000 or 10% of the grant - delete this if a non UJV partner] [\$200,000 or*



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*20% of the grant - delete this if a UJV partner], whichever is least. Any investigators proposing to access the Raine Study resources are required to contribute this access fee and include it in their grant application. For this grant application, the allocation to cohort curation costs is \$xxxx [insert relevant value for your grant here] over the grant period.*

## **For grants collecting new data at cohort follow-up**

### **Testing location – background information**

Where possible the Raine Study performs all testing on each participant on one occasion at a single location. Currently, and subject to grant success and further discussion, this location is the Raine Study House, UWA at 14-16 Parkway, Crawley. Core data collection costs (see below) have been estimated based on testing at a single location.

Testing at another location/occasion (e.g. for specialised testing) may be unavoidable. Such testing needs to be discussed with the Raine Study Management to ensure that participant burden is minimised. If such testing is required, additional core data collection costs will be incurred in order to cover costs associated with additional recruitment, scheduling and co-ordination [0.25FTE to 0.5FTE Research Assistant].

### **Data collection, cohort assessment – background information**

Recruitment, review and data collection from the Raine Study cohort participants is co-ordinated and conducted by the Raine Study team\*.

Appointment of data collection staff is coordinated through the Raine Study team.

Grant funding obtained for contacting the cohort, data collection and the conduct of the proposed cohort review will be transferred to the Raine Study to enable pooling of resources to contribute to the funding of the Raine Study team.

The cohort follow-up generally collects data over a 3 year period.

Grant funding for personnel associated with cohort follow-up (i.e. the Raine Study team) needs to cover a 3 year period. This is to accommodate a 3 month pre-data collection period (for training, assessment protocols, ethics applications, etc.) and a three month post-data collection period for data entry, cleaning, consolidation, etc.

\*The Raine Study team consists of the Raine Study specific follow-up coordinator, and experienced recruitment and research assistants (RAs). The costs of core data collection in grant applications cover the costs of this team. Additional RAs are recruited where necessary for the period of cohort assessments to collect project-specific data. These additional RAs must be budgeted for in grant applications if a project requires additional specific data collection.

### **The Raine Study core data collection costs**

The Raine Study team is responsible for:





- All follow-up management requirements, including budgeting and cost management, quality control and risk management.
- Planning, development, co-ordination, management and organisation of cohort follow-up assessments.
- Establishing and maintaining cohort representative involvement in planning, conduct and reporting of the project.
- Procurement of follow-up equipment and resources.
- Development of participant informed consent process.
- Development of adverse event and other standard operating procedures
- Participant recruitment including appointment scheduling, tracking, reminders.
- Participant consent.
- Data collection, data entry and data quality control.
- Collection of core longitudinal physical assessment including height, weight, blood pressure, biological samples and the collection of core questionnaire data including socio-economic status, general health and development.
- All other aspects of follow-up co-ordination including researcher liaison.

A cohort follow-up cannot proceed unless there is a minimum of 4 FTE RA's (this includes the co-ordinator) funded at PSP2 to perform these tasks.

## Staffing requirements for a cohort follow-up

This should be included in all grant applications.

### *Collection of new assessment data*

**All grants proposing to collect new data at follow-up are required to request funding for:**

- **One full-time recruitment officer (1.0 FTE) (PSP1)** for cohort recruitment and scheduling, for a 3 year period.
- **One full time research assistant (1.0 FTE) (PSP2)** for core data collection, for a 3 year period.

The need for a 3 year appointment is to accommodate a 3 month pre-data collection period (for training, assessment protocols, ethics applications, etc.), 2.5 years of data collection, and a three month post-data collection period for data entry, cleaning, consolidation, etc.

The justification for each grant asking for 1 full time (1.0FTE) recruitment officer and on 1 full-time (1.0FTE) RA is based on an estimated 2 to 3 grant applications being successful.

Funds obtained for the Raine Study team are transferred from each successful grant to the Raine Study to enable pooling of resources to contribute to the funding of the Raine Study team.

If data are proposed to be **collected at a site separate** from the main data collection venue, applicants must request funding for:

- **One additional part-time (0.25 FTE OR 0.5 FTE) RA (PSP2)** for a 3 year period.

A separate site involves additional recruitment and booking procedures. Funding for this individual is transferred to the Raine Study to enable pooling of resources to contribute to the funding of the Raine Study team. If the second appointment is complex and work intensive, then 0.5 FTE recruitment is required.

All grants proposing to **only collect questionnaire data** at follow-up must request funding for:

- **One half-time (0.5 FTE) RA (PSP2)** for both recruitment and core data collection for a 3 year period.

This is to accommodate a 3 month pre-data collection period (for training, assessment protocols, ethics applications, etc.), 2.5 years of data collection, and a 3 month post-data collection period for data entry, cleaning, consolidation, etc. Funding for this individual is transferred to the Raine Study to enable pooling of resources to contribute to the funding of the Raine Study team.

If the **questionnaire data involves face to face interviews or any method other than online self-completion**, then a 1.0 FTE (RA) PSP1 must be included.

## The Raine Study project-specific data collection costs

Each grant application must **request separate funding** to cover the costs of any project-specific measurements. This includes any additional personnel required to perform the measurements.

## The Raine Study biological samples

All grants proposing to use/collect blood or other biological samples are required to request funding for:

- **a half-time (0.5 FTE) phlebotomist (PSP1)** for a 3 year period.
- any consumables associated with blood collection, preparation and storage (e.g. syringes, test tubes etc.).
- specific assay costs.

## Summary of costs related to grant applications

### Grants applications using previously collected data

Application must include the Raine Study cohort curation and access fee.

## Grant applications to collect new data

Application must include the Raine Study cohort curation and access fee.

And include funding for:

- 1 FTE (PSP1) cohort recruitment, for a 3 year period.
- 1 FTE (PSP2) for data collection, 3 year period

*In addition* project specific data collection must include additional funding for:

- X FTE (PSP2) to cover project specific data collection, for a 3 year period.
- 0.25 – 0.5 FTE (PSP2) recruitment if data collected at a different site, for a 3 year period.
- 0.5 FTE (PSP1) phlebotomist if biological samples are collected, for a 3 year period.

Grants wishing to collect **only** self-completed questionnaire data need to include:

- 0.5 FTE (PSP2) recruitment and core data collection, for a 3 year period.

**Note:** The above data collection staffing requirements are based on an estimated 2 to 3 grant applications being successful

## Ethics application – background information

A single ethics application will be submitted for any cohort follow-up. This is submitted through the Raine Study to the UWA Human Research Ethics Committee (HREC). This will be co-ordinated centrally by the Raine Study follow-up coordinator with input from the investigators of all successful grants involved in funding the cohort review. All lead investigators will need to contribute towards this ethics application in terms of preparing scientific rationale, assessment protocols, questionnaire components etc.

### *Ethics application – suggested wording for grant applications*

*The applicants will work closely with the Raine Study to submit an application to the Human Research Ethics Committee.*

## The Raine Study cohort representativeness – background information

Cohort representativeness for Gen2 has been extensively evaluated, with details published in a cohort profile. Investigators are encouraged to cite this paper in their grant application.

*Straker L, Mountain J, Jacques A, White S, Smith A, Landau S, Stanley F, Newnham J, Pennell C and Eastwood P. (2017). Cohort Profile: The*





“The representativeness and presence of potential biases in the cohort have been examined with three sets of analyses. Eligibility and consent rates at the recruiting clinics were evaluated. Comparisons were made between the cohort participants and the Western Australian population at birth, childhood (year 8), adolescence (years 14 and 17) and young adulthood (years 20 and 22). Comparisons were also made between cohort participants and non-participants for all follow-ups.

At the time of recruitment, to assess whether the Raine Study cohort was representative of the population presenting at the recruitment sites, 6 months of clinic records in the middle of the recruitment period were audited. In the 131 clinic sessions 1420 women presented as new attendees and 707 (50%) were eligible. Reasons for ineligibility were: 36% were > 20 weeks gestation; 8% had language difficulties, 4% planned to deliver elsewhere and 2% had psychosocial problems precluding long term follow-up. Of the 707 eligible, 633 (90%) agreed to participate during the audited period (3).

At birth, the characteristics of the Raine cohort were compared with those of all live births (excluding Raine births) in Western Australia during the three year recruitment period utilising data from the WA Department of Health Midwives Notification System and Hospital Morbidity Database. Comparisons were made of birth weight, gestation age, neonatal nursery admission, pregnancy complications, Caesarean sections, maternal age, parous status, marital status, and race. Overall, the characteristics of Raine participants were similar to all Western Australian contemporaneous births except that Raine Study participants had slightly more pregnancies with complications and caesarean deliveries, and had more first time mothers and unmarried mothers (See Table1).

At the 8-year follow-up the characteristics of participating cohort families were compared with the Year 2001 Western Australian population census data (see Table 2). Demographic factors compared included family structure, state of residence, parents' place of birth, education, labour force participation and occupational status, income level, and language spoken at home. Overall differences between Raine study and WA population families were small except for more Raine parents residing in WA, being born overseas, more with post-secondary and tertiary education and in clerical/retail occupations, and less parents having low incomes.

At the 14 and 17 year follow-ups the cohort family characteristics of participants were compared with Year 2006 Western Australian population census data of families living in Western Australian with 15-17 year old children, as this was the most appropriately representative Western Australian demographic for comparison for either follow-up (see Table 3). Demographic factors compared included family structure, parents' place of birth, education, labour force and occupational status, income level and an index of advantage/disadvantage. Overall, the characteristics of the Raine families were similar to contemporaneous Western Australian families. There were no substantial differences in proportions of family structure, and an index of socio-economic advantage/disadvantage. There were more Raine families living in urban areas and with tertiary education. At 14 years there were more Raine parents in clerical/administrative occupations and middle incomes and at 17 these

differences were reduced with a shift of Raine parents to technical and professional occupations and higher incomes.

At the 20 and 22 year follow-ups the characteristics of cohort members participating in data collection were compared with contemporaneous Year 2011 Western Australian census data of 20 and 22 year old males and females living in Western Australia, as the most appropriately representative Western Australian demographic for comparison (see Table 4, and supplementary Tables 1 and 2 show sex specific comparisons). Demographic factors compared included: family structure, education completed, labour force status, occupation, work hours, and income level. Overall, most comparisons showed the Raine cohort had similar proportions to all Western Australian young adults. Exceptions with more marked proportional differences (>10%) indicated the Raine cohort at 17 years had more employed in clerical/retail, more working 40 or more hours a week, and more with higher incomes.

To assess any attrition bias the characteristics at infancy of participants and non-participants were compared at each follow-up (see Tables 5, 6 and 7). In general, the proportions of participants and non-participants across a number of infant characteristics remained constant across all follow-ups. An exception was a gradual reduction in participation of infants of Aboriginal and Torres Strait Islander ethnicity. (Family characteristics are compared in the companion profile paper on the parents – Generation 1.)”

Cohort representativeness for Gen1 has been covered to some extent in the Gen2 profile paper, and this is now also complimented with a Gen2 profile paper. Investigators are encouraged to cite this paper in their grant application.

*Dontje, M., Eastwood, P., & Straker, L. (in press). Cohort profile: The Western Australian Pregnancy Cohort (Raine) Study - Generation 1 International Journal of Epidemiology, BMJ Open.*

### *The Raine Study cohort representativeness – suggested wording for grant applications*

*An extensive assessment of the representativeness and presence of potential biases in the Raine Study cohort has been conducted. This has included comparison of the participants with the Western Australian population at birth, childhood, adolescence and young adulthood, along with comparisons between those participating and not participating at all follow-ups. In general the cohort was representative across a broad range of sociodemographic characteristics such as educational attainment, labour force status, occupational, income levels, family structure, area of residence, SEIFA index of relative advantage and disadvantage, and place of birth of parents/carers in comparison to Australian Bureau of Statistics census data on the Western Australian population of similar age. Similarly, in general, at each follow-up the proportions of participants and non-participants across a number of infant characteristics remained constant.*



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## Sample size – background information

The current Raine Study phenotypic dataset contains more than 30,000 measures as well as over 20 million genetic variants on each cohort participant.

Antenatal data were collected from the mother at around 18 weeks of pregnancy, at 34 weeks and at birth. Information was collected from the fathers at 34 weeks.

Gen1 data has subsequently been collected at perinatal, 1, 2, 3, 5, 8, 10, 14, 17, and 26 year follow-ups.

The Gen2-perinatal, 1, 2, 3, 5, 8, 10, 14, 17, 20, 22 and 27 year follow-ups have involved extensive collection of data through questionnaire and clinical examination of participants.

The Gen2 cohort is currently undergoing the 28 year follow-up, with 1200 participants expected to participate.

Gen0 is currently participating in their first data collection, involving questionnaires and clinical assessments.

A sample of Gen3 participated in a Gen3-27 year sub-study data collection, also involving questionnaires and clinical assessments.

### *Sample size – suggested wording for grant applications*

*The Raine Study estimates that 1200 Gen2 participants will complete assessments at the follow-up at age 31. This is based on 1234 of the available cohort (n=2086) participating at the 22-year follow-up (60% participation rate, 1234/2086).*

## Follow-up numbers

For Gen2 or Gen1 follow-ups we estimate that 1200 participants will complete the next assessments and ask all grants to budget accordingly. Therefore, we recommend that calculations of statistical power are based on a sample size of 1200.

For other generations please discuss with the Raine Study Management.

## The Raine Study consumer representation – background information

Cohort retention through consumer involvement and consultation is paramount to the success of the Raine Study. The Raine Study access fee contributes towards the costs of ongoing consumer involvement.

The Raine Study first established a consumer representative group consisting of ten Raine Study participants in 2008 and they met regularly with Raine Study Management and provided an important consultative and collaborative role on research proposals and cohort management issues. In 2017 a new Consumer Advisory Committee was established, with representation at the senior governance,

management, science and translation committees and portfolios of the Raine Study. The group continues to be active and has a broad remit for ensuring the Raine Study priorities and activities align with the values, desires and interests of the participants.

For new research proposals, investigators discuss research ideas in detail with the representative group and the Raine Study team to determine acceptability to the cohort, refine research questions and protocols and appreciate value of proposals to the participants.

In addition to the information provided to the representative group, regular feedback is provided to all participants through newsletters for participants.

The Raine Study informs participants of individual results within strict confidentiality protocols. The Raine Study has established feedback protocols in place and access to supportive networks in the clinical community if necessary for circumstances where participants may need support and advice.

Broader community involvement occurs through promoting healthy outcomes and publications and media releases, including on the Raine Study website and social media.

### *Consumer representation – suggested wording for grant applications*

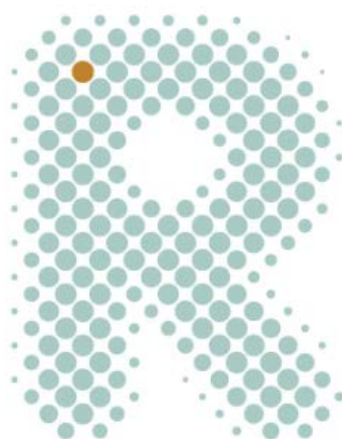
*Cohort retention through consumer involvement and consultation is paramount to the success of the Raine Study. The Raine Study access fee also contributes towards costs of maintaining consumer involvement.*

*The Raine Study has an active Consumer Advisory Committee that provides a consultative and collaborative role on research proposals, consenting, data collection protocols and cohort management. Along with the reference group, a wider group of participants provide input for researchers during the cohort assessment planning process. Overall results are communicated to the participants through newsletters and booklets. Media releases are used to promote health outcomes to the wider community. The Raine Study website provides access to information, publications and media releases for consumers and the wider community.*

### *Participant access to study results – suggested wording for grant applications*

*The Raine Study informs participants of their individual results and advises participants where necessary to access clinical review. Published group level research results are communicated to the participants through regular newsletters and the Raine Study website. The Raine Study has strict confidentiality protocols in relation to participant contact and support.*

End of Document



the  
Raine  
Study

One of us  
could change your life