



Ethics Committee approval for projects using the Raine Study data and/or biosamples

The Raine Study is an Unincorporated Joint Venture (UJV) whose Board is responsible for its governance, custodianship and control of its assets. The University of Western Australia (UWA) acts as the UJV's Centre Agent.

The Raine Study has collected data and biosamples from multiple generations of participants on many separate occasions (follow-ups) over the past 30 years. Each new follow-up has received Human Research Ethics Committee (HREC) approval that was specific for a given follow-up. To decrease the administrative burden associated with HREC approval for Raine Study projects, the UWA HREC has provided a single 'overarching' approval that recognises all previous HREC approvals under which previous data and/or biosamples were collected.

This UWA HREC approval was received on 29 April 2020 and provides a single consolidated approval (RA/4/20/5722) for use of research data and/or biosamples held in the Raine Study data collection. Use of this HREC approval has been provided on the basis that the release of Raine Study data and/or biosamples for a specific project has been approved by the Raine Study. This means that all projects need to have undergone the Raine Study governance and reviewing processes before a project can be submitted to a HREC. These processes are described in [the Raine Study website](#) and [the Raine Study Researcher Engagement Policy \(REP\)](#).

Ethics Committee approval for projects using existing data and/or biosamples

- Seek project approval from the Raine Study. The Raine Study team works with all researchers to develop their projects (The Raine Study Researcher Engagement Policy item 2.0 and the Raine Study website). Often researchers are unaware or unfamiliar with the Raine Study data and/or biosamples. By working with the Raine Study team early in the project design phase, many potential future issues are avoided. All new projects are submitted via the Raine Study Online Submission System (ROSS) and reviewed firstly by the Scientific Management Committee (REP Item 5.0) and secondly by the Scientific Review Committee (REP Item 6.0). Provisional or final project approval is provided by the Raine Study UJV Board, either directly or as delegated to the Scientific Review Committee.

Seek project approval from a HREC. A researcher can only submit a project to a 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 a [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.

- Based on the [National Statement](#) (NS 3.1.62), all projects need to receive approval from a 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 UWA HREC 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 full HREC review. For an indication of research requiring full HREC review refer to the [National Statement](#) (NS 5.1.6)

Thus, every new project using existing Raine Study data and/or biosamples must now have its own HREC approval/reference number. The lead researcher is responsible for providing a copy of the project's HREC approval/reference number to the Raine Study team via ROSS.

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

- Previously, any project wishing to collect new data and/or biosamples in Raine Study participants was 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. Both of these approvals continue to be required.
- Usually a study 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 a 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.

Thus, each new project involving collection of new data and/or biosamples must have its own HREC approval/reference number. The lead researcher is responsible for providing a copy of the project's HREC approval/reference number to the Raine Study team via ROSS.

Ongoing update of consolidated UWA HREC approval for existing Raine Study data and/or biosamples

Each time any new data and/or biosamples are collected, the Raine Study management will apply to the UWA HREC to update the single consolidated HREC approval (RA/4/20/5722), in order to allow use of all existing data and/or biosamples, including any newly acquired data and biosamples. In order to add new data and/or biosamples to the Raine Study collection in the first instance a request to amend HREC approval RA/4/20/5722 will be submitted. In some cases a new application may be required, however once that application has been approved, the UWA HREC will roll that approval number into RA/4/20/5722.