

Human Ethics Exemption Form

What is Exempt from Ethical Review?

In line with the updated [National Statement on Ethical Conduct in Human Research 2023](#) (National Statement), RMIT Human Ethics has developed an exemption form to be submitted via REP (Research Ethics Platform). These will be considered by the Ethics Coordinators of each College. This process replaces the self-assessment exemption pathway.

As per the updated National Statement, research that may be exempt from review by the RMIT HREC or one of the College Human Ethics Advisory Networks includes that which:

- a) Carries *Lower Risk** to participants and community **AND**
- b) Satisfies one or more of the exemption criteria

(* 'Lower Risk' refers to the updated risk continuum/levels of risk in the National Statement).

What do I need to consider for exemption?

Criterion 1: Risk to participants

The [National Statement](#) describes research which may be exempt from ethics review as involving *no risk of harm or discomfort*. To be exempt from ethical review, your project should not involve any risks (actual or potential) relating to:

- **Physical harm:** including injury, illness, pain or death
- **Psychological harm:** including feelings of worthlessness, distress, guilt, anger, fear or anxiety related, for example, to disclosure of sensitive information, an experience of re-traumatisation, or learning about a genetic possibility of developing an untreatable disease
- **Devaluation of personal worth:** including being humiliated, manipulated or in other ways treated disrespectfully or unjustly
- **Cultural harm:** including misunderstanding, misrepresenting or

- misappropriating cultural beliefs, customs or practices
- **Social harm:** including damage to social networks or relationships with others, discrimination in access to benefits, services, employment or insurance, social stigmatisation, and unauthorised disclosure of personal information
- **Economic harm:** including the imposition of direct or indirect costs on participants
- **Legal harm:** including discovery and prosecution of criminal conduct

Criterion 2: Exemption conditions

Where there is no risk of harm or discomfort, the research must meet one (or more) of the following conditions to be considered exempt from ethical review:

- The research involves the use of collections of information or data from which all personal identifiers have been removed prior to being received by the researchers and where researchers:
 - Will not attempt to re-identify those with whom the information or data is associated;
 - Will take all reasonable steps to prevent re-identification of the information or data for unauthorised purposes or access to the information or data by those who are not authorised; and
 - Where any sharing of any research data during or after the project will not create any additional risks of re-identification of the information or data;
- The research is restricted to surveys and observation of public behaviour using information that was or will be collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research;
- Is conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only;
- The research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics

If your research does not meet the [National Statement](#) criteria for risk to participants and exemption conditions, then it is not eligible for exemption from ethical review and you must submit an application in [REP](#).

When should I complete my exemption form?

Your exemption should be granted before your project commences. You must retain proof of exemption for your records as you may need to provide this later.

Key things to remember when completing the self-assessment:

- The responsibility for submission of the exemption resides with the Principal Investigator.
- Your exemption should be reviewed throughout the duration of your research project, amendments to your research may impact on its risk level and may require future review by an ethics committee even if it was exempt at the start.
- If you obtain data from a data custodian, you must retain all permissions and conditions documentation along with your project records.

FAQs

Q1. Do external investigators (i.e. non-RMIT staff or students), need to be listed on the exemption form?

No. Only RMIT investigators (staff or students) need to be listed on the exemption form.

Q2. Do I need to apply for an exemption if I am not conducting human research?

The exemption pathway applies solely to human research, that is research “conducted with or about people, or their data or tissue” (National Statement, p. 7). Please review the National Statement and contact the human ethics team to discuss: humanethics@rmit.edu.au

Q3. My project is using ethnography or auto-ethnography as the means of data collection, is it exempt?

There is no simple determination if a data collection method is exempt. Auto-ethnography is not likely to be exempt, whilst some forms of ethnography may or may not be exempt. Please contact the human ethics team to discuss your specific circumstances.

Q4. In 1.1.2 of the risk assessment, the third exemption criteria notes that surveys collected without ‘personal identifiers’ (e.g. survey respondents’ name, address, birthdate, etc.), and that are highly unlikely to cause distress may be exempt. My survey is not collecting personal identifiers, is it exempt?

There are many other factors besides the use of personal identifiers that need to be considered if a human research project is to be assessed as exempt from review, and there is no simple formula that would fit in a FAQ to determine this absolutely. Please contact the ethics team at humanethics@rmit.edu.au to discuss your specific circumstances.

Please note, if your project is determined not exempt, you will need to submit a full application. The timeline from submission to approval is approximately three-months.

Q5. Do I need to fill out the whole form and complete the data management plan template?

Yes. If the form or data management plan is incomplete, it will be returned to you to rectify. The determination of whether the project meets the exemption criteria cannot occur without a complete form including full details.

Q6. If the data set I am accessing requires a signed licensing agreement before I have access to the data, should I submit an exemption form before or after this is completed?

After. You will need to outline confirmation that you can access the data at 2.2.1.5 in the exemption form. You will also need to outline appropriate data management in your data management plan uploaded at 2.2.1.8.

If you need approval from RMIT as a requirement of your licensing agreement before you are able to access the data, please contact the human ethics team: humanethics@rmit.edu.au

Q7. I have submitted my exemption form, what happens now?

The Ethics Coordinator of your college will consider the form within 3-5 business days. If there are further queries they will return the form to you with comments to address. If your exemption is confirmed you will receive notification via REP with an attached Notice of Exemption. If your project is found to be not exempt you will receive notification via REP and you may need to submit a full application if you wish to proceed with the project. Please note, we recommend allowing three months from submission of a full application to approval.

Q8. My exemption was confirmed, but my project has changed, what do I do now?

The exemption form cannot be amended. Please contact the human ethics team to discuss, as you will need to submit a new exemption form. If the change/s elevate the risk of the project and render it no longer exempt you will need to

submit a full application.

Q9. Do I need to register an externally confirmed exemption with RMIT?

No. Only RMIT projects that may meet the exemption criteria can be submitted via the RMIT exemption pathway.

Q9. My question is not listed here/I don't understand/I am confused.

Please contact the human ethics team to chat, humanethics@rmit.edu.au
We look forward to hearing from you!

Time constraints or a lack of awareness or understanding are not acceptable reasons to claim exemption from the requirement for ethical review where projects carry risks greater than inconvenience.

What is not eligible for exemption?

Research that is not eligible for exemption includes:

- Research that is lower risk or higher risk as defined by the [National Statement](#).
- Research conducted with populations defined as vulnerable under the [National Statement](#).
- Research involving biospecimens (stored and prospectively collected).
- Research that involves individually identifiable or re-identifiable data.

How to complete the Human Research Ethics Exemption form:

The Principal Investigator should:

1. Read this guidance note and consider whether their research meets the criteria to be exempt from review.
2. Complete the Human Research Ethics Exemption form in [REP](#), completing each question in full.
3. Submit your

completed Human Ethics Exemption form for governance review by a Research Governance and Ethics Coordinator.

4. You will receive initial feedback within 3-5 working days. This may involve asking for further information to assist in the review process.
5. Once the review is complete, you will either receive confirmation that your application is exempt, or you will receive guidance that your application is not exempt. In cases where an application has been found to be not exempt, you may have to submit a new human ethics application for CHEAN or HREC review.

Further information

Further information can be found in the [Human Research Ethics Policy Procedure](#).

For further advice on this topic or other human research ethics matters, please email humanethics@rmit.edu.au. A Research Governance and Ethics Coordinator will assist you who can offer expert advice.