

Human Ethics Minimal Risk Checklist PSYCHOLOGICAL SCIENCES

Assessing risk is an important part of an ethics application. Themis provides a variety of checklists to help researchers navigate risk assessment and to help them determine what kind of application is most appropriate. One common key distinction is between minimal and non-minimal risk projects. Below you will find a variety of considerations that will help you decide whether your project is minimal risk.

As you work through your submission in Themis, you will first come across a set of broad conditions that will be used to determine whether a minimal risk application is permissible and whether additional modules need to be completed. Some projects are, in virtue of their general methods, ineligible for minimal risk application, e.g. drug trials, those involving the collection of biospecimens.

If your project's general methods permit eligibility for minimal risk, then you will have to consider more specific project parameters for risk assessment. The checklist items listed below appear in at later stages of the Themis application. Researchers should review the checklist items below to assess whether their project would be eligible for review as minimal risk. Student researchers should discuss the checklist items with their supervisors. If researchers answer "YES" to **ANY** of the items in the checklist the project would normally **not be eligible** for minimal risk review.

There is the possibility of making a special case for minimal risk assessment if they have answered "YES" to an item in the checklist but still believe that because of the particular nature of the project and/or the participants the project may still be eligible for minimal risk review. The Human Ethics Advisory Group will then assess whether the project can be reviewed as minimal risk. It is the HEAG that decides if a project is minimal risk.

If in doubt, please have the responsible researcher (i.e. the faculty member) discuss the issue with Dr. Simon Laham (Chair of MSPS Human Ethics Advisory Group) before the application is submitted.

If there is a risk that your research will uncover something that will require an intervention (e.g. depression, an eating disorder, a previously undiagnosed health issue, criminal conduct etc.) then normally a minimal risk application would not be appropriate.

Additionally, if the potential harm to the participant, *even if the harm is unlikely to occur*, is beyond the level of "discomfort" then it normally would not be a minimal risk application. So if there is the potential that as a result of participating in your experiment the participant may experience strong negative emotions or that your experiment may exacerbate an existing psychological condition (e.g. depression, an eating disorder or PTSD) then it is unlikely to be considered minimal risk. Additionally, if there is a possibility that the participant might feel "used" or unhappy with their conduct then this would also indicate that your application could not be considered minimal risk.

Bearing the above paragraph in mind, it is very important to consider whether your experiment contains any deception or whether you otherwise conceal the true purpose of the experiment. In some cases, concealing the true purpose of the experiment may not preclude your application being minimal risk. Indeed, it is common not to tell the participants the exact hypotheses that you intend to test. However, if in concealing the true purposes of the experiment you are encouraging individuals to participate who may not have participated had no concealment taken place or if, through concealment, you are introducing an additional risk that the participant may be adversely affected by participation, then your project is unlikely to be considered minimal risk. For example, if in your experiment an experimenter were to pretend to be a participant and in that role try to encourage the real participant to do something that he might regret (e.g. make a socially unacceptable statement), and this were to be concealed from the participant, then such a project is unlikely to be considered minimal risk. In deciding whether a project is minimal risk the HEAG and HESC place a lot of weight on the Plain Language Statement and whether that statement accurately informs the prospective participants of all likely risks. If the deception in your experiment requires the Plain Language Statement not to mention significant risks then it is unlikely that your application will be considered to be minimal risk.

1. EXTERNAL REQUIREMENTS

Is the research being funded by an overseas agency such as NIH or other American Government agencies that require Ethics Committee review that involves community representation? (NOTE: select NO if your research is being funded by the ARC or NHMRC) YES NO

2. RISK ASSESSMENT

A. Are any of the following topics to be covered in part or in whole?

- research about parenting YES NO
- research investigating sensitive personal issues YES NO
- research investigating sensitive cultural issues YES NO
- explorations of grief, death or serious/traumatic loss YES NO
- depression, mood states, anxiety YES NO
- gambling YES NO
- eating disorders YES NO
- illicit drug taking YES NO
- substance abuse YES NO

- self report of criminal behaviour YES NO
- any psychological disorder YES NO
- suicide YES NO
- gender identity YES NO
- sexuality YES NO
- race or ethnic identity YES NO
- any disease or health problem YES NO
- fertility YES NO
- termination of pregnancy YES NO

B. Are any of the following procedures to be employed?

- Involves personal info from a Commonwealth department YES NO
- Involves personal info from a State department YES NO
- Involves personal info from a non-government organisation YES NO
- Use of medical data where participants can be identified YES NO
- Involves sensitive health information (e.g., genetic info) YES NO
- Deception of participants YES NO
- Concealing the purposes of the research YES NO
- Covert observation YES NO
- Audio or video recording without consent YES NO
- Recruitment via a third party or agency YES NO
- Withholding beneficial treatments or methods of learning YES NO
- Any psychological interventions or treatments YES NO
- Administration of physical stimulation YES NO
- Invasive physical procedures YES NO
- Infliction of pain YES NO
- Administration of drugs YES NO
- Administration of other substances YES NO
- Administration of ionising radiation YES NO
- Tissue sampling or blood taking YES NO
- Collecting body fluid YES NO
- Genetic testing YES NO
- drug trials and other clinical trials YES NO

C. Risk to the researchers

Identify any risks to the researcher (e.g. research undertaken in unsafe environments or trouble spots)? YES NO

3. VULNERABILITY ASSESSMENT

Does the research specifically target the following?

- those suffering a psychological disorder YES NO
- those suffering a physical vulnerability YES NO
- people highly dependent on medical care YES NO
- minors without parental or guardian consent YES NO
- people whose ability to give consent is impaired YES NO
- residents of a custodial institution YES NO
- people unable to understand information statement YES NO
- members of a social group with special needs YES NO
- those in dependent relationship with researchers YES NO
- identifiable participants without specific consent YES NO
- Aboriginal or Torres Strait Islanders YES NO

4. OVERSEAS RESEARCH RISKS

Does the research involve any of the following?

- research being undertaken in a politically unstable area YES NO
- research involving sensitive cultural issues YES NO
- research where criticism of government is dangerous YES NO