The University of Melbourne
Human Research Ethics
Human Ethics Minimal Risk Checklist
Melbourne School of 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. Patrick Goodbourn (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 PSTD) 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

1. EXTERNAL REQUIREMENTS

Is the researcher 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 ARC or NHMRC)

2. RISK ASSSESSMENT

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

- research about parenting
- research investigating sensitive personal issues
- research investigating sensitive cultural issues
- explorations of grief, death or serious / traumatic loss
- depression, mood states, anxiety
- gambling
- eating disorders
- illicit drug taking
- substance abuse
- self report of criminal behaviour
- any psychological disorder
- suicide
- gender identity
- sexuality
- race or ethnic identity
- any disease or health problem

- fertility
- termination of pregnancy

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

- use of personal data obtained from Commonwealth Gov't Department/agency
- use of personal data obtained from State Gov't Department/agency
- involves use of personal information from a non-government organisation
- involves sensitive health information (e.g. genetic information)
- deception of participants
- concealing the purposes of the research
- covert observation
- audio or visual recording without consent
- recruitment via a third party or agency
- withholding from one group specific treatments or methods of learning, from which they may "benefit" (e.g., in medicine or teaching)
- any psychological interventions or treatments
- administration of physical stimulation
- invasive physical procedures
- infliction of pain
- administration of drugs
- administration of other substances
- administration of ionising radiation
- tissue sampling or blood taking
- collecting body fluid
- genetic testing
- drug trials and other clinical trials

3. VULNERABILITY ASSESSMENT

C. Does the research specifically target participants from any of the following groups?

- those suffering a psychological disorder
- those suffering a physical vulnerability

- people highly dependent on medical care
- minors without parental or guardian consent
- people whose ability to give consent is impaired
- residents of a custodial institution
- people unable to give free informed consent because of difficulties in understanding information statement (eg language difficulties)
- members of a socially identifiable group with special cultural or religious needs or political vulnerabilities
- those in dependent relationship with the researchers (eg lecturer/student, doctor/patient, teacher/pupil, professional/client)
- participants able to be identified in any final report when specific consent for this has not been given
- indigenous Australians

4. OVERSEAS RESEARCH RISKS

- research being undertaking in a politically unstable area
- research involving sensitive cultural issues
- research where criticism of government is dangerous