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 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 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)

2. **RISK ASSESSMENT**

   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

   □ YES □ NO

Minimal Risk Checklist Reviewed February 2017
• 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