The purpose of the classification scheme is to identify for full consideration, research where participants may be exposed to risk, and to assist in the faster processing of projects where participants are considered to be at minimal or no risk. The classification scheme is an aid to efficiency and in no way absolves investigators from conducting their research in an ethical manner.

There are three levels:

**Risk Level 1**

It is recognised that some very low risk projects may not require review by the RMIT Human Research Ethics Committee (HREC), but should be reviewed by a Portfolio HRE Sub-Committee. This enables the portfolio to monitor the research in order to ensure that proper practice has been followed and to ensure that the project is both designed and carried out appropriately. Risk level 1 research is reviewed and approved by the HRE Sub-Committee (HRESC) in your Portfolio. If your group does not have links with an academic portfolio, the application should be submitted to the RMIT HREC.

**Definition:** Research classified risk level 1, refers to non-invasive projects where there is no apparent risk to participants above the everyday norm and where participants are not identified.

Examples are:

- research involving the use of standard tests and questionnaires administered appropriately to normal adult populations, and where data are recorded in such a manner that the participants are not and cannot be identified;
- research or evaluative procedures involving observation of public behaviour on unidentified participants, where data are recorded in such a manner so that they are not and cannot be identified;
- research or evaluative procedures involving collection of existing publicly available data, documents, records or specimens; and
- research carried out in an educational setting using groups of participants (rather than individual participants), where data are recorded in such a manner so that they are not and cannot be identified.

Here are some examples of recent research projects in risk level 1:

*Professional development needs specific to teaching*

Ethical consideration: respondents to this questionnaire were anonymous.

*A pilot study investigating the correlation between childhood fractures and head injuries and the development of Adolescent Idiopathic Scoliosis*

Ethical consideration: this study used records that had had all identifying details removed before being made available to the researcher.
Risk Level 2

Risk level 2 research is reviewed and approved by the Human Research Ethics Sub-Committee in your Portfolio but it is subject to the endorsement of the RMIT HREC. If there is no Portfolio Sub-Committee the research should be submitted to the RMIT HREC.

Definition: Research classified risk level 2 refers to projects where participants are considered not to be exposed to physical, psychological and social risk above the everyday norm, but which may contain an element of slight risk to participants. It would include, for example:

- non-invasive research involving minors as participants where there is individual or one-to-one interaction between investigator and participant;
- research where participants are in a dependent relationship to any of the researchers;
- aside from other factors which may warrant a level 3 classification, the use of diagnostic ultrasound and magnetic resonance imaging (MRI) will be considered as minimal risk as long as the research protocol meets acceptable clinical standards; or
- research which involves the recording of personal information; and
- any other research involving human participants which is not classified as risk level 1 or 3.

Here are some examples of recent research projects in risk level 2:

- **Reasons some patients refuse epidural anaesthesia and/or analgesia: a grounded theory enquiry**
  Ethical issues: privacy & consent, dependent relationship (patient & caregiver / investigator), participants in a vulnerable condition.

- **Employment problems of recent skilled immigrants in Australia**
  Ethical issues: privacy & consent, possible distress to participants.

- **An Examination of SMB re-sellers in the Australian and NZ PC markets**
  Ethical issue: investigator worked for a competitor company - need for disclosure in the plain language statement

Risk Level 3

Risk level 3 research is reviewed by the Portfolio Human Research Ethics Sub-Committee, but must be considered and approved by the RMIT HREC. Any clarifications or amendments proposed by Portfolio Sub-committee must be made to the satisfaction of the representative of the Portfolio Sub-committee, before submitting your application to the RMIT Human Research Ethics Committee.

Definition: The classification risk level 3 applies to all research which may involve risk to participants and/or researchers above the everyday norm. It includes research which:

- uses intrusive techniques, including some personality assessment tests;
- may cause discomfort (either physical, psychological or social) beyond normal levels of inconvenience;
- examines potentially sensitive or contentious areas, such as studies of body image or sexuality;
- uses therapeutic techniques;
- seeks disclosure of information that may be prejudicial to participants (for example, which has the potential to be incriminating);
- involves any physical intervention or removal of body fluids or tissues (such as blood or urine samples, biopsies);
- involves a clinical trial of any drug, therapeutic product or biomaterial;
- involves circumstances where the purpose of the study is not fully disclosed – deception;
- uses a highly vulnerable participant population for example - intellectually disabled individuals, people who have undergone trauma, or psychologically disturbed individuals or
- involves the collection, use or disclosure of identified personal, health or sensitive information without the consent of the individuals whose information it is.

Here are some examples of recent research projects in risk level 3:

*Human skeletal muscle Il6 production and its effect on insulin dependent and independent skeletal muscle glucose uptake*

Ethical issues: invasive procedure – muscle biopsy, discomfort.  
Contingency planning required – first aid.

*Effects of a worksite physical activity program for adults with an intellectual disability*

Ethical issues: privacy, a vulnerable group of participants for whom special arrangements must be made to ensure informed consent; some participants may be sensitive about their weight and some may find the cardiovascular fitness test to be stressful.  
Contingency planning required - first aid.

*The lived experience of adolescent war victims who are at risk of developing post traumatic stress disorder*

Ethical Issues: privacy, working with minors, the interview could trigger unresolved issues and distress.  
Contingency planning required – counselling, debriefing.

*Victims’ perspectives on processes of sexual assault and attempted sexual assault*

Ethical Issues: privacy, the interview could trigger unresolved issues and distress.  
Contingency planning required – counselling, debriefing.

*Evaluation of a Hepatoma surveillance and treatment program in patients with cirrhosis*

Ethical Issue: privacy - involved use and disclosure of identified health information without the consent of the individuals whose information it was.  (The public benefit of the research must be weighed against the infringement of health privacy principles and only the RMIT HREC is authorised to do this.)