

St Mary's University Ethical Application System (Three Tiers)

For research involving human participants, staff and students will be required to complete an *Application for Ethical Approval* (research or teaching form), the purpose of which is to review whether there are any potentially significant ethical risks.

Undergraduate student and taught Masters student applications (except students who are also staff – see below) must initially be sent to the relevant supervisor and may be signed off at level 1. If a student application is signed off at level 1 the Faculty ethics representative must be notified. Student applications which cannot be approved at level 1 must be sent to the Faculty ethics representative to decide whether they can be signed off at level 2, or should be considered by the Ethics Sub-Committee at level 3.

PhD students, and staff who are also Masters or PhD students, must submit their ethics application to a Faculty ethics representative via their supervisor. The Faculty ethics representative may sign it off at level 1 or 2 or forward it to the Ethics Sub-Committee for consideration at level 3.

Staff research ethics applications must be submitted to a Faculty ethics representative who may sign it off at level 1 or 2 or forward it to the Ethics Sub-Committee for consideration at level 3.

Ethics applications involving dietary supplements (unless the substance and amount might occur in everyday life) must always come to level 3; randomised controlled trials that are health related or involve clinical procedures must always come to level 3. Where there is any doubt about the level of approval, the application must be approved at the higher level.

Level 1 – Consideration

A low risk is defined as one where potential harm to participants is no greater than that encountered in everyday life. It also includes research where the researcher(s) are working with participants from vulnerable groups (in line with the Safeguarding Vulnerable Groups Act 2006) but will not be alone with them at any time i.e. they will be overseen at all times by an experienced individual who holds a DBS check undertaken within the last 3 years, and will not be storing images, videos or personal details of children under 18 years of age.

Level 2 – Consideration

A medium risk is defined as one where potential harm to participants is greater than that encountered in everyday life. It also includes research where the researcher(s) are working with participants from vulnerable groups and/or they will be storing images, videos or personal details of children under 18 years of age, but they have produced satisfactory DBS check(s) on themselves undertaken within the last 3 years.

Level 3 – Detailed Consideration

This applies to activities that require careful scrutiny due to their potential for physical or psychological harm. A high risk is defined as one where there is a possibility that significant harm will be caused to participants (e.g. an adverse reaction to a drug or supplement, physical damage/injury, psychological or emotional harm). It also includes research where the researcher(s) will be alone with participants from vulnerable groups and/or will be storing images, videos or personal details of children under 18 years of age.