

# HREC Standard Operating Procedure

## 1.1 Application of Values and Principles of Ethical Conduct

### Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 1 of the National Statement on Ethical Conduct in Human Research (2023). The HREC ensures that the Values and Principles of Ethical Conduct are upheld and applied to the ethical review of research, specifically: respect, research merit and integrity, justice and beneficence.

### Definitions

**Respect** is defined as the recognition that each human being has value in him or herself, and that this value must inform all interactions between people; the value of human autonomy, including the capacity to determine one's own life and makes one's own decisions; protection for those with diminished, or no autonomy and the promotion of empowerment to assist people where it would be wrong to do so.

**Research Merit and Integrity** is defined by the level of merit which can be achieved through the conduction of the research, the integrity of the researchers conducting the research, and the justification of ethical human involvement in the research.

**Justice** is defined as either **distributive** or **procedural** justice. Distributive justice is defined as the fair distribution of the benefits and burdens of the research. Procedural justice is defined as fair treatment in the recruitment process and the review of research.

**Beneficence** is defined by assessing and taking account of the risks of harm and the potential benefits of research to participants and the wider community; in being sensitive to the welfare and interests of people involved in their research; and in reflecting on the social and cultural implications of the research.

### Procedure

The values of respect, research merit and integrity, justice and beneficence have become prominent in the ethics of human research in the past six decades, and provide a substantial and flexible framework of principles to guide the design, review and conduct of such research.

To ensure the application and practical expression of these values and principles, all members of the HREC must be familiar with the National Statement on Ethical Conduct in Human Research (2023), and in particular, Sections 1.1 to 1.13, and ensure that these guidelines are applied when reviewing any research protocol involving humans.

Here, the HREC must ensure that all research:

- Is justifiable and has merit
- Has potential benefits (either direct or in future) that outweigh the risks
- Has an appropriate method
- Is based on appropriate literature, where relevant
- Is designed to ensure respect for participants
- Is designed to ensure the safety of participants
- Is appropriately conducted and supervised
- Is carried out with integrity


In order to ensure a thorough account of the consideration of these key principles, a Professional Spokesperson and Lay Spokesperson will be appointed to undertake a specialised review of each protocol at each meeting, in keeping with national and local guidelines. The appointment of two spokespeople serves to ensure a minimum of two in-depth reviews from different perspectives for delivery to the full committee. Once both spokespeople have had the opportunity to discuss the application and any concerns, discussion is opened to the full committee with the expectation that at least one member from each category provides a formal comment on the ethical acceptability of the proposed research. If additional expertise is required to ensure the application of values and principles, comment will be sought outside the HREC membership from appropriate persons, groups and/or communities.

To guide the process of ethical review, spokespeople are provided with a copy of the Research Governance Unit 'Review Checklist' and Pro Forma which notes the key principles of all statutory and other guidelines, and serves as a prompt for review and discussion. The use of this checklist is not mandatory, however when this tool is used by members, it must be retained by the Research Governance Unit as a supplement to the official minutes.

## Reference Documents

- The National Statement on Ethical Conduct in Human Research (2023)
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
- Australian Code for the Responsible Conduct of Research (2018)

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