

# Ethical Considerations Marsh

Weeks 8 - 11 | Ethical Considerations Marsh



From an **ethics** perspective, have a think about what the issues are, in relation to your proposed methods for:

- Sampling
- Data collection
- Data management

Based on your decisions for the above issues, how will you now address the following principles in **research ethics**?

### **Respect for your participants':**

- Autonomy / individual responsibility (informed consent)
- Privacy (anonymity / confidentiality)
- Justice / beneficence (doing good as well as preventing or minimising potential harms)
- Human vulnerability / personal integrity
- Cultural diversity

Clearly describing the **ethical considerations** related to your proposal is important, as this is an area of key concern for members of a **Human Research Ethics Committee** (HREC).

# Application of ethical principles

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As a researcher, you have duty of care to your participants. How will you address these issues:

## Autonomy (informed consent)

- Right to an informed decision
- Use of understandable language and terms
- Description of potential risks and discomforts
- Competent to provide informed consent
- Vulnerable populations (involvement of Guardianship Board)
- Right to withdraw from the study

Let's consider some of these in more detail...

## Risks and Benefits

### For participants:

- Estimate their level of risk in participating
- Can the research adversely affect them?
- Could the research induce any psychological distress?
- Will the true purpose of the research be concealed?
- Could the research cause any physical harm?
- Are they your patients?
- Is research expected to directly or indirectly benefit them?

# Participants

All study participants have the above rights.

In addition, certain types or categories of participants require particular attention and care; commonly identified from a research perspective as **vulnerable** populations; for example:

- Age range - children
- In a teacher-student relationship with researcher or associates
- In an employer-employee relationship
- In any other dependent relationship
- Wards of the state
- Prisoners
- Members of the armed services
- Mentally ill
- Intellectually impaired
- Unconscious or critically ill patients
- Under the Guardianship Act 1987
- In doctor-patient or health care giver-receiver relationship

## Respect for privacy

**Anonymity - no person, including the researcher/s, can identify individuals as participants**

**Confidentiality - the identity of participants will not be linked to the information they provide**

## Data storage

### Consider the issues for security of participant data:

- Separating identifying information from other participant data (use of study IDs, separate datasets)
  - De-identification in study reports (use of pseudonyms)
  - Secure storage of data
    - participatn consent forms
    - paper-based data
    - electronic data
  - Requirements from Government agencies (eg NHMRC) and HRECs
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# HREC processes | ethical approval policies and resources

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## **Will your proposed study be ethical?**

While you are not required to submit your proposal to a relevant HREC for this Subject, it is important for you to understand and appreciate the steps and processes required for approval, prior to commencing any participant recruitment and data collection.

## Questions

1. Information about selected committees:
    - Title of committee:
    - Contact details:
    - Frequency of meetings
    - Date next submission due
    - Date of next meeting
  2. What information does the Committee provide about 'Nil / negligible risk' proposals?
  3. Based on your methods, what level of HREC approval does your proposal require?
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## Low and negligible risk

Some proposed research may have certain characteristics and impact on study participants that can be deemed minimal, such as:

Level of risk	Description
Low risk	<ul style="list-style-type: none"><li>• only foreseeable risk is one of discomfort</li><li>• e.g. minor side-effects of medication, discomforts related to measuring blood pressure, anxiety induced by an interview</li></ul>
Negligible risk	<ul style="list-style-type: none"><li>• no foreseeable risk of harm or discomfort</li><li>• any risk is not more than inconvenience to participants</li><li>• e.g. filling in a form, participating in a survey, giving up time to participate in a research activity</li></ul>

These types of studies may be eligible for **expedited ethical and scientific review** if the research involves:

- Questionnaires / general surveys on non-controversial, non- personal issues and where respondents are not identified;
- use of information from existing data collections where identity of the person cannot be ascertained from the information;
- access to individual medical records or stored information stored, where participant consent is not required

How do you judge your proposal? What is the **level of burden and risk** for study participants? This self-assessment needs to be clearly described in your research proposal.

# Ethical considerations | Application to your proposal

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## Writing your ethical considerations narrative

So, what are the ethical principles that relate to your research proposal?

- Autonomy / individual responsibility (informed consent)
- Privacy (anonymity / confidentiality)
- Justice / beneficence (doing good as well as preventing or minimising potential harms)
- Human vulnerability / personal integrity
- Cultural diversity
- Security of data

# Resources (required) Hill

Weeks 8-12 | Resources (required) Hill



## Budget

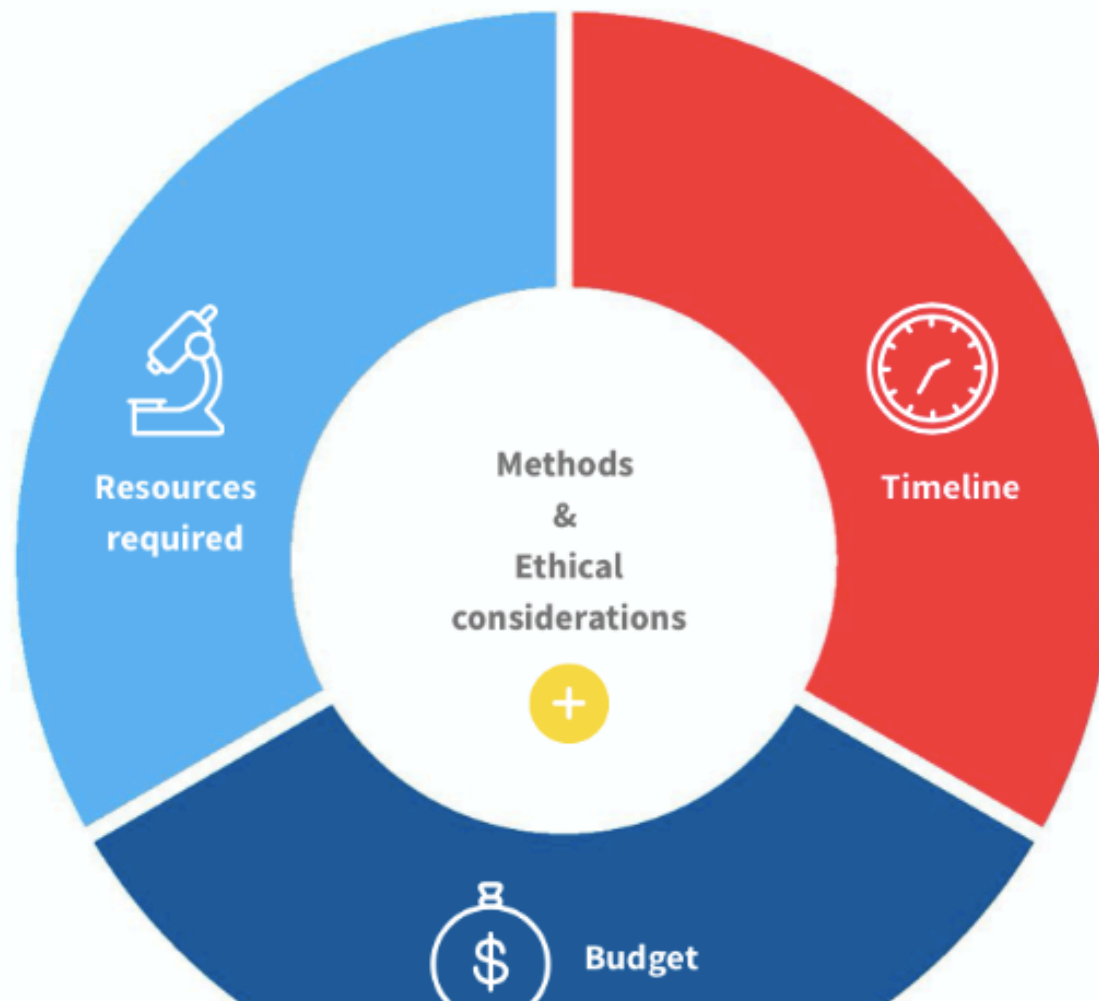
As discussed earlier in our journey, a budget is not required for submission to a real **Human Research Ethics Committee**. This information may however be required for governance approval from the Local Health District or similar agency or body in which the study is proposed. This is referred to as **Site Specific Approval (SSA)**, where a Head of Department will approve use of facilities or other resources for the study.

# Developing a feasible study proposal

Weeks 8-12 | Resources (required) Hill

## Requirements for approval

Consider the following elements in the Figure below, and their links to the proposal **methods** and **ethical considerations**.



# Resources required

Weeks 8-12 | Resources (required) Hill



Consider the following elements; what is required for your proposal?

## Personnel

- Investigators (usually not funded for the study)
- Project staff (funded), HDR student/s)

## Equipment

- New equipment required (not available in practice)
- Use of existing equipment (need governance /Departmental Head approval?)
  - Meets study requirements?
  - Any study costs for use? (reimbursement to the facility for use)
- eg computer hardware, software

## Consumables

- Usage / costs for measuring study outcome variables
- Travel costs to collect data?
- Other costs for participant recruitment / management
- Other data collection costs; eg printing / mailing costs, communications
- HREC submission costs?

Consider every element and activity involving study setting, participants, data collection...



What costs are involved?

# Budget

## Weeks 8-12 | Resources (required) Hill

As noted earlier, a budget section is not normally required for a HREC submission, although some information may be required for 'Site Specific Approval' from the study site as part of the ethics approval process.

## Preparing a budget

List each budget item with indicative costs

- Link research staff costs to
  - skill level required
  - Hours per week and time period required to complete their tasks (e.g. may only be required for data recruitment, or data collection, not the whole study timeframe)
- Include quotes for equipment / consumables (**Note: not required for Assessment 4**)

Provide a short, comprehensive **justification for each item**

- Link to study outcomes and feasibility

## Calculating staff costs

If a Project Officer / Research Assistant is required, consider what skilset is required to complete their activities. Costs may be based on the Higher Education Worker role in a University, or a clinical role in a health service, for example.

**Higher Education Worker (HEW):** Examples of the qualifications, experience and work activities for a research-based role might include:

- Graduate (degree) or professional with some experience
- Relevant technical or specialist experience
- Under general direction, work as part of a research team, manage a research project, provide technical skills

# Budget Examples

Weeks 8-12 | Resources (required) Hill

Patient comfort in the intensive care unit: a multicentre, binational point prevalence study of analgesia, sedation and delirium management

Crit Care Resusc 2013; 15: 213-219

Component	Comment
Design	Cross-sectional analysis
Participants	n=569 patients in 41 ICUs
Data collection	Point prevalence day
Resources	Staff (project manager, research assistant) In-ICU data collection Consumables

# Timeline

Weeks 8-12 | Resources (required) Hill



Consider these research activities, in two parts - **prior to ethics submission**, and **after ethics approval**; what needs to be done for your proposed study? and how long do you estimate for each activity?

## Prior to HREC submission

### Research team

- Skill set required?
- Time commitment expected from each team member

### Proposal development

- Time to develop - number of iterations? (think about how much time you have spent on your proposal for this subject)

### Site preparation

- Identify and discuss with key stakeholders

### HREC / governance preparation

- Timelines for approval
- Informal discussions with HREC secretariat

## HREC approval / study implementation

### Site preparation for participant recruitment / data collection

- Employment / induction / orientation for any research staff
- Staff information / education

### Participant recruitment

- Planned recruitment period, based on desired sample size and 'throughput'

### Data collection

- Time required for data collection per participant
- Length of data collection for participants, based on design and data collection / measurement points

### Data management / analyses

- Time required to enter and manage data in a database, perform quality checks (audits of data quality) and to perform data analysis

### Report writing

- HREC report; conference abstract / presentation development; manuscript development