

Writing your submission

Following these four important principles will make it easier for you to prepare an effective submission.

1: Be Clear

Sections of the application template ask you to explain aspects of your project.

Clarity of meaning is of paramount importance throughout the submission. If the meaning of a certain passage is not clear, approval may be delayed while the reviewers seek clarification.

Be direct

Use simple words or phrases and short sentences. Follow the conventional rules of punctuation and grammar. (Most word processing software will query obvious mistakes in these areas, but if you have any doubts you should seek advice.)

Organize your material

Clarity is achieved not only by the way you express yourself but also by the way you organize your material.

Begin by jotting down a rough outline of your submission in point form. Arrange your material according to a logical sequence and a ranking of importance.

A sequence of sentences which all relate to a topic should be grouped as a paragraph. If a major topic is covered in several paragraphs you could consider indicating the fact by inserting a heading.

Where possible each sentence should contain one thought or statement. Keep sentences short (15 to 20 words). Putting too many thoughts into a single sentence makes it difficult to understand.

When a sentence needs to contain a list of any extent this is usually best formatted as a series of dot points, e.g.:

- head and shoulders
- chest
- abdomen
- thighs

Formatting aids clarity Appropriate formatting will make your submission easier to assess. It can also be used to draw attention to those parts of the submission you consider most important

Unless already determined by the template you are using, the normal text spacing should be at least 1.5 lines.

A new paragraph should be indicated either by indenting the first word or by inserting a half-line space before it.

Used sparingly, a variety of text faces can be employed to indicate emphasis. Important words or phrases could be set in italic or underlined. Longer passages could be set indented, to indicate their importance.

Long passages are sometimes best broken up by sub-headings, provided these conform to a consistent pattern.

2: Be Concise

Don't be afraid of brevity. A wordy document will not be more convincing than one which is concisely expressed (on the contrary).

Do not include information which is not directly relevant to the reviewers, lay readers or participants. The explanation of complex processes does not necessarily require complicated sentences. There is no concept so formidable that it cannot be summarised. Stick to your point and avoid repetition.

3: Know Your Audience

Parts of your submission will be directed to readers who are familiar with the language of medical research. Other parts (such as the lay summary in Module 1 and the Participant Information and Consent Form) will be intended for a lay readership. It is essential that sections directed to lay readers are written in plain language.

Plain language means using words that can be understood by an average person or a Year 8 student. When medical terms have to be used they should be explained in common words the first time they appear. Remember that even words used commonly in medical research (such as 'placebo' and 'double blind') may not be understood by lay readers.

Acronyms should be used only for the purpose of brevity and the term or name should be written out in full the first time it is used, e.g., 'Human Research Ethics Committee (HREC)'.

Guidelines for preparing a lay summary are on page 4.

4: Check and Revise

Try to finish the draft of your submission well before the deadline, and then put it aside. If you believe it would be useful, ask an appropriate colleague to read and comment on the draft.

After a short break, or when you have received any comments, read the draft again. Returning to it after an interval will make it easier to notice and correct any errors or omissions.

Plain Language Summary guidelines

Maximum length 400 words. Use language suitable for Year 8 student. Where appropriate, the summary should answer the following questions:

1. What condition is being treated or investigated?
2. What is the purpose of the study?
3. What is the function of the drug or the nature of the treatment compared with the current treatment?
4. What is the proposed research design?
5. Who are the participants and what commitment is required of them?
6. Who else (e.g. sponsor, professional body) is involved in the research?

Some examples of 'good' and 'inappropriate' plain language summaries are given on the next pages

EXAMPLE OF GOOD LAY SUMMARY

<p>What condition is being treated or investigated?</p>	<p>This research is aimed at people who have SBS (sudden posterial descent), often called ‘slack bottom syndrome’. In this condition a person’s buttocks slip down the back of their legs, making it difficult or uncomfortable for the sufferer to sit down or keep their pants up. While the condition can be rectified by gluteoplasty (placing implants in the buttocks to give them a firmer outline) this procedure is known to cause severe side effects.</p>
<p>What is the purpose of the study?</p>	<p>The standard treatment for SBS is a weekly dose of Superglue (cyanoacrylate). While achieving a permanent cure in 6 out of 10 patients, 4 out of ten experience a sudden return of the condition during a hot shower or prolonged immersion in water. The aim of this study is to compare the efficacy of an experimental drug, Araldite (polyepoxide) with the standard treatment.</p>
<p>What is the function of the drug or the nature of the treatment?</p>	<p>Trials with Araldite have suggested that it has the same adhesive quality as Superglue while being unaffected by heat, and that it does not lose potency during prolonged immersion in water. This study aims to determine if taking 5 mg of Araldite once a month is as safe but more effective than a 10 mg dose of Superglue once a week.</p>
<p>What is the proposed research design?</p>	<p>Those taking part will be randomly allocated (such as by the toss of a coin) into two groups. Each group will be given a supply of tablets, to be taken at home, and a diary. Neither group will know what medication the tablets contain. Group A will receive Superglue tablets to be taken once a week. Group B will take one Araldite tablet once a month.</p>
<p>Who are the participants and what commitment is required of them?</p>	<p>The study will involve 550 patients across Australia of which 150 will take part at Box Hill. Participants will be equal numbers of males and females aged over 55 (the age at which SBS commonly appears) who have been diagnosed with SBS. Participants will be asked to record in their diaries any adverse incidents and to return the diaries after twelve months.</p>
<p>Who else (e.g., sponsor, professional body) is involved?</p>	<p>The study will be sponsored by Selleys, the manufacturer of Araldite and the researchers have received a grant from the Better Bottoms Foundation.</p>

EXAMPLE OF POOR LAY SUMMARY

At the 2009 International SBS Conference held in Bogota, the challenge of managing SBS was identified as major health concern throughout the Western World with the incidence rising 175% and rated by the United Nations Health Organisation 17th on the World Posterial Disorders Scale.

- Unnecessary background.
- Condition not explained.
- Sentence too long.
- No punctuation.

Although the outcome for patients with SBS has improved in the last decade poor risk patients rating between 7 and 12 on the International Prognostic Index and experiencing frequent periods of sub-aqueous immersion at temperatures $>38^{\circ}\text{C}$ are seen to be in need of a novel treatment regime which can offer an extension of the standard dosage intervals without simultaneous increase in negative outcomes.

- Medical terminology not explained.
- Standard treatment not explained.
- Symbol $>$ not appropriate.

A reported 40% reversion rate in patients exhibiting sudden posterial descent suggests there is a need for innovative treatment beyond gluteoplasty or cyanoacrylate therapy.

- Treatments not explained in lay terms.

Accepting the desirability of alternative therapy options the purpose of this randomised, blinded, multi-centre Phase III study is to estimate the relative efficacy/safety of cyanocrylate 10 mg weekly as a single agent v polyepoxide 5 mg monthly within the patient population.

- Research design not explained in lay terms.
- Drugs not explained.
- Medical jargon.

Studies using Araldite as a single agent therapy have indicated the superiority of a thermosetting epoxide polymer that evidences a reaction between epichlorohydrin and bisophenol-A to bring about retrograde gluteal positioning which occurs more rapidly than with cyanoacrylate 10 mg.

- Proprietary name not explained.
- Sentence too long, complex.

550 patients will be recruited for this study in which those in both treatment arms will record their adverse outcomes using the 21-point Blottwell Fogworth inventory index rating applied at baseline and assessed by calculation of the study team at the conclusion of the study.

- No mention of recruitment, sponsor, composition or requirements of participants.