**Guidelines for Final Letters to Participants**

**Key points**

The RCH HREC advises that you should communicate your study results to participants wherever possible. This can help foster participants’ trust in the study process and give them a more positive experience overall.

The [final letter](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Informed_consent_and_plain_language/) is a key way of communicating your study results to participants.

Our [plain language resources](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Plain_Language_Resources/) can help you write a clear and accessible final letter. The Example Final Letter will be particularly useful.

When you have drafted your final letter, please email it to our office. Do not submit the final letter on ERM. Our Plain Language Adviser will provide feedback on your letter. When the letter is suitable for participants, the Plain Language Adviser will issue you with an approval certificate confirming you can distribute the letter to participants.

If another HREC has given your study ethical approval, see section 8c of these guidelines.

**Why do I need to write a final letter to participants?**

Communicating your study results to participants is a key part of the study process. Doing so can help you meet your obligations under the [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023), and foster participants’ trust in, and satisfaction with, the study.

 At the start of the study, the Principal Investigator should let participants know how the study results will be communicated to them.

In some cases there may be a valid reason not to communicate the study results directly to participants – for example, if participation was via an anonymous survey. If this is the case, you should outline and justify this position in the initial ethics application.

**What are the purposes of the final letter?**

The final letter needs to:

1. communicate the study results to participants in plain language
2. thank participants for the time and effort they have invested in the study.

**Who should draft the final letter?**

The organisation that has the study results should draft the final letter. In commercial trials this will usually be the sponsor. If the sponsor drafts the letter, the Principal Investigator at the RCH should review the letter. The Principal Investigator should make sure the letter complies with RCH guidelines and expectations around final letters and plain language communication.

**When should I draft the final letter?**

You should draft the final letter when the study results are available. This might be after the study is closed and the final report has been submitted to the Human Research Ethics Committee. It is the Principal Investigator’s responsibility to ensure that participants are sent a final letter.

**What are the steps for writing a final letter?**

1. Make sure the **study results** are available.
* Your study results may not be available until after your study is closed. If this is the case, you can send your letter after the study is closed.
1. Determine the **most appropriate organisation** to write the final letter.
* The organisation that has the study results should draft the final letter. In commercial trials, this will usually be the sponsor. For a multisite trial it may be the Coordinating Principal Investigator.
1. Determine who needs to be sent a final letter.
* Generally, you should send a final letter to **all study participants**.
* You should consider whether to send a letter to participants who withdrew from the study. In some cases it will be appropriate to send them a letter. In other cases it may not be – for example, if the participants have withdrawn from the study and explicitly asked you not to contact them again.
* You should consider whether any participants may have died since taking part in the study. If any participants are **deceased**, consider whether it is appropriate to send the parent/guardian a final letter. If you believe that it is appropriate to send them a letter, make sure you tailor your letter to their circumstances.
1. Draft a letter in plain language that **summarises the key study results** and thanks participants for their time.
* You should draft your letter with reference to the plain language resources on the RCH Research Ethics and Governance website, particularly the **Example Final Letter.**
* Make sure you summarise the study results in plain language. You should not simply provide website or refer to journal articles that contain the study results. Your final letter should in itself provide a concise summary of your study results.
* Remember to include a **version number** in the footer of your letter.
1. Email your draft letter to the Research Ethics and Governance Plain Language Adviser.
* Include the **HREC number** in the subject heading of your email.
* Provide a **clean Word copy** of your final letter. The Plain Language Adviser cannot review your letter if it is a PDF.
* **Let the Plain Language Adviser know whether your study is single site or multisite. If your study is multisite, list the site names in your email.**
* Do not submit the final letter on ERM.
1. The Plain Language Adviser will review and process your letter.
* The Plain Language Adviser may ask you to revise your letter. If you need to revise your letter please remember to **update the version number** in the footer of your letter. Please then email the updated letter to the Plain Language Adviser.
1. The Plain Language Adviser will give you official confirmation that you can send your letter to participants.
2. **Distribute your letter.**
	1. **If your study is single site:**
* After your letter has been approved by the Plain Language Adviser, send it to participants.
	1. **If your study is multisite, with RCH the lead ethics committee:**
* After your letter has been approved by the Plain Language Adviser, the study teams should add in site-specific details to the letter. These site-specific details could include the name of the site, site letterhead and site contact person.
	1. **If your study is multisite, with RCH governance only:**
* The Principal Investigator should contact the lead site to check if they are sending participants a final letter. If they are sending a final letter, the letter should be approved by the lead ethics committee.
* Please provide a copy of the letter to the REG office via ERM as a Site Governance Amendment, including the HREC approval letter. If the study has closed in ERM please email a copy to our office.

**Further reading**

* National Institutes of Health, ‘[Clearly Communicating Research Results across the Clinical Trials Continuum](https://www.nih.gov/health-information/nih-clinical-research-trials-you/clearly-communicating-research-results-across-clinical-trials-continuum#:~:text=Researchers%20should%20assure%20participants%20that,Getting%20Started%20or%20Brushing%20Up).)’ (2016).