# Beyond the Form logo with which features a purple circle with an icon of a doctor and a participant each standing on a cliff edge with two speech bubbles between them. On the left side features the CT:IQ logo and on the right is the VCCC Alliance logo

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# **Ethics Review of Clinical Research Communications**

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# The Beyond the Form Project

This guidance has been developed by the CT:IQ and VCCC Alliance [Beyond the Form](https://ctiq.com.au/current-projects/project-9) project team. The Beyond the Form project encourages researchers to make two-way communication with participants a standard part of clinical research projects. This guidance responds to questions from researchers about how they should seek approval for communications with participants. It is part of a broader [toolkit](https://ctiq.com.au/beyond-the-form-toolkit/) for people designing and conducting clinical research projects.

# Purpose

Good communication with participants is an important part of any clinical research project. Ethics review bodies can encourage researchers to communicate with participants throughout clinical research projects. This document discusses options for ethics review bodies to review and approve ongoing communications between researchers and participants.

# Background

Researchers and ethics review bodies give a lot of thought to the information people receive when they are considering taking part in a clinical research project. This is an important part of communicating with participants. However, communicating with participants during a project is also important. Ethics review bodies should create clear expectations for communication between participants and their research team. This should be supported by an ethics review process that is proportionate to the clinical risk of the research project.

Research projects usually plan how they will communicate with participants about project logistics and data collection. Yet, communication with participants can and should go beyond this to include, for example:

* expressions of gratitude
* educating a participant about their health condition
* updates about the progress of the project
* sharing a participant’s individual results with them
* access to research outcomes (lay summaries, project reports and/or full publications).

Participants often see these types of communication as marks of respect and as evidence that their contribution to the research project is valued. Strong communication also helps to build and maintain trust in clinical research more generally. This can improve future engagement and recruitment efforts.

The CT:IQ and VCCC Alliance Beyond the Form project has gathered views from research staff and participants on communication in Australian clinical research. One of the challenges researchers have raised is uncertainty about the ethics review requirements for communication activities. For instance:

* which kinds of communication materials need ethics review?
* what level of detail do researchers need to give?
* at what time(s) will the materials be reviewed?

Researchers were concerned that seeking approval for communication activities could lead to long delays. Greater clarity on ethics review pathways may encourage researchers to use ongoing communication activities.

## Regulatory requirements

Under the National Health and Medical Research Council National Statement on the Ethical Conduct of Human Research (2023, National Statement), an ethics review body must review all material related to recruitment and consent before its use (3.1.19 and 5.2.15). Researchers should create plans to share individual results with participants (3.1.63-4) and provide lay summaries of their findings (3.1.70-1). Researchers should also present information to participants in ways that are easy for participants to understand (5.3.6).

ICH-Good Clinical Practice (2016, ICH E6(R2)) also requires ethics approval for the materials that will be read by people considering taking part in a research project (1.1.2). Under the current draft ICH E6(R3), sponsors should describe the method by which they will give information to participants (ICH E6(R3) Annex 1, 1.1.2d) and should consider giving researchers information at the end of the project about their participants’ treatments and a summary of the outcome (ICH E6(R3) Annex 1 3.17.2c).

The Australian National Clinical Trials Governance Framework (2022, the Governance Framework) guides public and private health service organisations on conducting clinical research. It states that information should be given to research participants in ways that are engaging and accessible, in plain language, and available in different languages and formats (e.g., Actions 2.3, 2.8 and 2.10). Participants should receive information about clinical research in a way that is appropriate for them. Researchers should use a variety of ways to communicate with participants (Action 2.8).

Communication for clinical trials that involve therapeutic goods are also regulated under therapeutic goods laws. In Australia, these include but are not limited to the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (Cth) and its interpretation in the Medicines Australia Code of Conduct. Sponsors for trials covered by these laws are responsible for making sure their communication plans are compliant. Among other things, sponsors should not be seen to promote unapproved therapeutic goods.

Sponsors also may need to seek review by others in their organisation (such as communication or marketing departments) or at the sites where the research will be conducted (such as research governance offices).

## Partnering with Consumers

The National Statement, the Governance Framework, and the NHMRC Statement on Consumer and Community Involvement in Health and Medical Research (2016, currently under review) encourage researchers to involve consumers in the development of clinical research studies. One way for researchers to do this is by involving consumers in developing communication plans for a research project. Researchers should describe how consumers were involved, and why it was done this way, in ethics review applications.

## Ethics review in a changing world

Changes in technology such as Artificial Intelligence (AI) are making it easier for researchers to personalise how they recruit participants, and what information participants are sent. Research participants also have much more access to information from the internet. As such, ethics review bodies will not be able to review all the information that research participants have access to, or the specific words that are used in every communication. A principles-based approach to reviewing communication activities will allow for a more agile participant experience. It will also free up ethics review bodies and researchers from unnecessary review activities that don’t add value to the research, in favour of activities that will have a greater impact on patient safety and welfare.

# Planning for communication

Having a written communication plan can help researchers explain their approach to an ethics review body. Under the National Statement, an ethics review body must approve all materials that participants will see during recruitment and consent (see National Statement 5.2.15). An ethics review body also must approve the way in which researchers will communicate with potential participants to make sure these methods suit the target population (see National Statement 3.1.70-1, 4.4.5 and 5.3.6; ICH-GCP E6 R3 Annex 1 1.1.2d). Having a clear communication plan in the initial ethics application will provide an agreed understanding of how these communication activities will take place and be monitored. Where researchers follow an approved communication plan, usually they should not need to seek additional approvals from an ethics review body.

A communication plan can also assure research governance offices that researchers have the resources and funding to carry out their approach. Under the Governance Framework, research governance officers must also review the way in which researchers will communicate with potential participants (Governance Framework Action 2.3), including ways to receive and act on participant feedback about the communication they receive (Governance Framework Action 1.8, 1.13-14, 2.2). Understanding how, when, why and what researchers plan to communicate, and how participants can share their feedback with researchers, will help reviewers consider the risks and benefits of their planned approach.

Communication plans may be included in the main protocol or in a separate document. In a multi-site project, a communication plan may need to vary between research sites. These adaptations can be managed in the same way as local variations in a project’s Participant Information and Consent Form.

Some points to consider for common approaches to communication with research participants are listed below.

Contact point for participants: Participants should have a clear point of contact in the research team. Ideally, participants should receive all their communication from one person or a group using a common phone number and/or email address. Researchers should show ethics review bodies that staff are adequately trained and empowered to communicate about the research procedures, discuss any research results or outcomes, and follow up participant feedback with the researcher or sponsor. For example, communication training could be included in the protocol.

Including support people: Participants should be given the option to have project communication materials shared with a person they trust. This can support their understanding, particularly if there are barriers to effective communication, such as language, culture, or health status. Whether participants are seeking logistical, emotional, or decision-making support may change over the course of the project, so researchers should be able to record changes in participant preferences.

Progress updates**:** There may be a long time between when a participant enrols in a project and when any research outcomes are available. In these cases, researchers should share progress updates, such as the number of participants or active sites. This information is meaningful for many participants. Researchers may seek ethical approval for planned progress updates using a template that includes the planned content, communication mediums (e.g. a written document, a video, or a conversation with research staff), and what will trigger sending the update. Researchers should discuss with ethics review bodies whether:

* every update needs to be reviewed as an ethics amendment;
* review will be through another form of oversight (such as a Submission for Acknowledgement, or notification in the Annual Report);
* no further review is required.

Updates that contain only publicly available information that is non-promotional in intent (e.g., on a clinical trial registry, or in academic publications) or that focus on making participants familiar with the site or site staff, may not require individualised ethics approval.

Individual results: A participant’s results from research tests that are not part of standard care may still be valued by them. Researchers should develop an ethically defensible plan for which results they will share and when this will happen, in line with Element 5 of the National Statement, (3.1.62-4). The plan should include templates to show how any graphs or tables will be formatted and described, so that the clarity and relevance of the information to be given to participants can be reviewed. The Participant Information and Consent Form should tell the participant when they should expect to receive these results (e.g. within a timeframe after a procedure), and if there are opt-in or opt-out options for receiving these results.

Health literacy materials: Health literacy materials created as part of research interventions should have ethics review in the same way as any other research materials. However, the research team may also decide to share publicly available information with participants to improve their health literacy or as a marker of respect; for instance, newsletters or magazines relevant to a health condition being researched. If researchers are using publicly available materials, these can be listed in the communication plan without necessarily needing individual review.

Expressions of gratitude: Researchers may express their gratitude to participants through a thank you card or letter, a phone call or video message, or a certificate of completion. Expressing gratitude can be a powerful recognition of the contribution research participants make to the research endeavour. However, when done poorly they can also come across as tokenistic. Therefore, the timing and messages of expressions of gratitude should be designed with consumer representatives. Researchers may seek ethics approval for these messages by having a plan for the events which would trigger a message and the different text options. For example, they could list “thank you” messages for enrolment, key project milestones, and project completion. Unless there are significant changes to the wording of these texts or the status of the project, the benefit of additional ethics review of each instance is unclear.

Plain language summary of research outcome: Sharing the results or outcome of the research project with participants is recognised in Chapter 3.1, Element 6 of the National Statement as showing the ethical principles of respect, beneficence and justice. During the consent process, researchers should tell participants whether, and in what form, they will be able to access a summary of the research outcomes (National Statement 3.1.34). They should also tell participants when this information is likely to be available (3.1.70) and make sure that any outcomes shared with participants are provided in language that is easy for them to understand (3.1.71).

Sponsors are responsible for sharing the outcomes of the research with site researchers, who should then share them with participants. This pathway needs sponsors to maintain relationships with site researchers until a summary of the outcomes is ready for ethics review and distribution. If a researcher seeks to close a project before they have shared a plain language summary of the project outcomes, ethics review bodies should question them about how this information will be shared.

# Conclusion

The CT:IQ and VCCC Alliance Beyond the Form Project has heard a strong call from participants and regulatory bodies for more meaningful and timely communication with researchers throughout a clinical research project. However, we also need to avoid unduly increasing the administrative burden on ethics review bodies and research staff. Careful interpretation of the available guidance and solutions such as communication plans and templates can help to streamline processes and reduce administrative load, ensuring that meaningful and timely communication can take place without overwhelming researchers or ethics review bodies.

# Appendix 1: Checklist for ethics reviewers

When reviewing ethics applications, ethics review bodies should consider the following questions. The relevant information may be in the protocol, a separate Communication Plan, or in other supplementary documents such as templates.

1. Have the team worked with relevant stakeholders (including site staff and consumer representatives) to develop a communication plan?
2. Have the team sought to maximise the diversity of their participant pool through a flexible approach to communication (this may include considerations for people with limited smartphone or digital access, different cultural, linguistic or ethnic backgrounds, or different communication abilities)?
3. Is there a mechanism for participants to express their preferences for how they communicate with research staff? This may include:
	1. Language (e.g. multiple languages used, use of interpreters, and/or use of support people)
	2. Medium (e.g. email, SMS text or phone calls)
	3. Frequency (e.g. frequency of reminders or updates)
	4. Level of detail (e.g. only summary or essential information vs. all the information)
	5. The option to include support people in communications.
4. Has the language and formatting used in the submitted templates or materials been reviewed by consumer representatives to check that it is easy to understand, or has this been done by the ethics review body?
5. Is there a plan for how to update participants on the progress and outcomes of the research? This could be through providing research updates, sending participants a summary of the outcomes, hosting webinars or open day events, and/or hosting a website with progress information.
6. Is there a mechanism for staff to collect and respond to participant feedback, both to research and to communication activities (e.g. a central help desk. a participant experience survey, or regular reminders for participants to contact site staff with feedback)?

The communication plan should describe any materials that research teams will send participants during the research project, such as expressions of gratitude, individual results, educational health literacy materials, project updates, or project outcomes.

1. Will these materials need additional ethical review as amendments? This may be needed if the research project is high risk, or the messages are likely to change significantly from the original templates.
2. If site(s) are likely to close before a lay summary has been submitted for ethical approval, is there a plan for how participants will access this information?