# A banner featuring the Beyond the Form logo which is a purple circle with white graphic of two people communicating with speech bubbles. To the right is CT:IQ's logo and to the left is the VCCC Alliance logo.

# **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 project team. The Beyond the Form project seeks to encourage research teams to set up robust frameworks for two-way communication in the design and execution of clinical research projects. This guidance was developed in response to widespread questions about how to approach seeking approval for communications with participants.

# Purpose

Appropriate and effective communication with participants is an important aspect of any clinical research project. This statement is intended to assist ethics review bodies develop policies to facilitate researchers embedding ongoing communication with participants into clinical research studies. This statement proposes which communications with clinical research participants require prospective ethics review, and which could be dealt with through agreed communication plans, templates, or other oversight mechanisms.

# Background

Researchers and ethics review bodies often give extensive thought into what information research participants receive when they are considering participation in a clinical research project. While this is an important part of communication with participants, the manner in which research teams and participants communicate during a project and at its end is also crucial to the integrity of the research, to participant experiences, and to meeting participant expectations. Creating clear expectations, pathways and responsibilities for communication between participants and their research team should be encouraged and supported by a proportionate ethics review process.

Research projects commonly plan for communication with participants about logistics and data collection. Yet, communication with participants can and should go beyond this to include, for example:

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

Participants often value these types of communication as demonstrations of respect and as evidence that they are considered a partner in the research project. Communication between researchers and participants may also be enhanced by allowing for flexibility in the methods used to address participant preferences around the type of information they want to receive and also how they would like to receive that information (e.g., allowing options for using SMS text, phone calls, letters or emails as preferred).

The CT:IQ and VCCC Alliance [Beyond the Form project](https://ctiq.com.au/current-projects/project-9/) has identified and sought views from research staff and participants on ongoing communication strategies used in Australian clinical research. One of the challenges researchers have raised in implementing such strategies is uncertainty about the ethics review requirements for ongoing communication materials, including which channels and materials require ethics review, the level of detail required, and at what time. Similarly, researchers anticipated significant time required for review if they sought to amend the wording or modalities used for communications. These uncertainties and delays can lead to a reluctance to engage in ongoing communication, and inconsistency between sites in how communication is approached. In turn, this can impact the participant experience and the integrity of the trial data.

## Regulatory requirements

The National Health and Medical Research Council National Statement on the Ethical Conduct of Human Research (2023, National Statement) requires the review of all materials related to recruitment and consent by an ethics review body (3.1.19 and 5.2.15). It provides guidance for what researchers should consider in developing plans to share individual results with participants (3.1.63-4) and encourages researchers to provide lay summaries of research outcomes to participants (3.1.70-1). It also encourages researchers to consider how they present information to participants to facilitate their understanding of the content (5.3.6). The National Statement is silent on how research teams might otherwise advisably communicate with participants during and after their involvement in the research.

ICH-Good Clinical Practice (2016, E6 R2) also details that participant-facing material related to recruitment and consent needs ethics approval (1.1.2). Further, the current draft E6 R3 also states that sponsors should describe what channel will be used to provide information to participants (Annex 1, 1.1.2d) and should consider providing investigators with information about their participants’ treatments and a summary of the overall outcome, which could then be provided to participants (3.17.2c), so that the participant may have this information to help inform their future health care planning. Neither document addresses other types of information that researchers might provide and the context in which it would be provided.

The Australian National Clinical Trials Governance Framework (2022, the Governance Framework) provides extensive guidance for public and private health service organisations undertaking clinical trials. This includes setting up systems for ensuring information provided to research participants is engaging and accessible, in plain language, and available in different languages and formats (e.g., Action 2.3, 2.8 and 2.10). It requires that patients, consumers, and trial participants receive information they need relating to clinical trials in a way that is appropriate for them and recognises a variety of mechanisms should be used to meet the communication needs of the diverse consumer and community population. (Action 2.8). The Governance Framework explicitly gives an institution’s Research Office the role of ensuring that the institution has the capacity to support the project, which should include the capacity to undertake any communication activities specified in the research protocol or associated supporting documents.

Communication activities for clinical trials that involve therapeutic goods also intersect with therapeutic goods law and regulations. 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 these trials should be aware of the additional legal requirements regarding promotional activities and take steps to ensure compliance in their communication plans.

Sponsors should also be aware that they may need to seek review by others within their organisation (such as communication or marketing departments) or within the sites where the trial will be conducted (such as research governance offices). These reviews of communication plans should be secondary to the ethical considerations discussed here.

## Partnering with Consumers

There is strong encouragement from the National Statement, the Governance Framework, and the NHMRC Statement on Consumer and Community Involvement in Health and Medical Research (2016, currently under review) to include consumers in the development of clinical research studies. An appropriate application of this would include involving consumers from the target population in developing communication plans for a research project. The nature of the consumer involvement, and why this approach was chosen, should be documented in ethics review applications.

## Ethics review in a changing world

Changes in technology are allowing for greater personalisation of recruitment approaches, increased used of Artificial Intelligence (AI) for personalising information to an individual’s needs, greater shared decision making altering the conversations between consumers and clinicians, and greater access to information via the internet. It is unreasonable to expect that ethics review bodies will be able to assess all the information to which trial participants will have access, and the specific words that are used in those communications. A principles-based approach to review of communication activities will allow the possibility of a more personalised, improved participant experience. It will also free up ethics review bodies and research teams from administrative burden that may not add ethical value to the conduct of that research, in favour of activities that will have a greater impact on patient safety and welfare.

# Planning for communication

Documenting planned communications can be a useful way for a research team to explain their approach to an ethics review body and satisfy research governance offices that these activities will be properly resourced and funded. Understanding the proposed methods, materials and objectives of the project’s communication activities will help determine the risks and benefits involved. Ethics review bodies can then suggest adjustments to the proposed communication plan as proportionate to the risks involved in the research. These communication plans could either be incorporated into the main protocol or submitted for ethical review as a separate Participant Communication Plan, similar to submissions related to Data Management Plans.

All materials related to participant recruitment and consent require prospective ethics review (see National Statement 5.2.15). The channels of communication to be used during recruitment and consent, and throughout the project, should also be ethically reviewed to ensure that the options are suited to 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; and Governance Framework Action 2.3). This should include setting up channels for receiving and acting on feedback from participants about the communication they receive (Governance Framework Action 1.8, 1.13-14, 2.2).

Paragraph 5.3.6 of the National Statement outlines numerous considerations for how researchers present information to participants during the research project, with paragraph 4.4.6 further specifying the need to consider the communication needs of people highly dependent on medical care. A clear communication plan made available at the time of initial ethics review will best provide for an agreed understanding of valuable, ongoing communication activities. It will further minimise the need for researchers to submit protocol amendments or deviations to allow for ongoing communication activities later in the research pathway

Some considerations for specific types of communication channels and materials that could form part of a communication plan are listed below.

Contact point for participants: Participants should have a clear point of contact within their research team. Ideally, there should be one person (or a group using a common phone number and/or address) from whom participants receive all communication. Ethics review bodies should be provided with information to demonstrate that staff are adequately trained and empowered to communicate about the research procedures, can discuss any project results as appropriate, and able follow up any participant feedback with the site PI or sponsor. For example, this could be through including communication training in the protocol and listing the role in site ethics applications.

Including support people: Participants should be given the option to have project communication materials shared with a trusted person to support their understanding of these materials, particularly if there are any likely communication issues, such as those related to language, culture, or health status. Participant preferences for logistical or emotional support from these people may change over the course of their involvement, so there should be the functionality to adjust participant preferences during the project.

Progress updates**:** There may be a significant time between when a participant enrols in a project and when any outcomes from the research are available. This may be due to the project's duration, or the time taken to recruit the number of participants needed for data analysis. In these cases, it shows respect to the participant to provide updates on the progress of the project. Such updates, including the number of participants or active sites, are considered meaningful by many participants. Researchers could seek prospective approval from an ethics review body for planned progress updates via a template outlining the content that will be included, the channels that may be used (such as via a written document, a video or audio version of written content, or a conversation between research staff and the participant), and the triggers for sending this information. Researchers could usefully discuss with ethics review bodies whether every individual project update needs review via an ethics amendment; if another form of oversight (such as a Submission for Acknowledgement, or notification in the Annual Report) would be appropriate; or if no further review is required. For instance, updates that contain only information that is already publicly available and non-promotional in intent (e.g., on a clinical trial registry, or peer reviewed publications) or that are focused on increasing familiarity with the site, or site staff, may not require ethics approval for each instance.

Individual results: Results from research tests that are not part of standard care may still be of interest or medically relevant to research participants. Research teams should develop an ethically defensible plan for which results will be shared with participants and at what timepoints, in line with Element 5 of the National Statement, (3.1.62-4). The plan for the provision of individual results should be included in the protocol or as an appendix to the ethics submission. This plan (which may form part of the overall communication plan) should include templates to show the formatting for any graphs or tables and associated explanatory text, so that the clarity and relevance of the information to be supplied to participants can be reviewed. The Participant Information and Consent Form should provide information on the time points the participant would expect to find out about their own 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 to support research interventions should have ethics review as required for any other research materials. However, health literacy materials in the public domain (for instance, newsletters or magazines relevant to a health condition being researched) may also be usefully provided to research participants for informational purposes and as a marker of respect for participants. Provision of specified informational materials could be listed in the communication plan without necessarily warranting individual review.

Expressions of gratitude: Expressions of gratitude may be delivered at various timepoints in a project, such as 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 this can also come across as tokenistic and potentially be counterproductive, so the timing and messages should be co-designed with consumer representatives. Researchers could usefully seek ethics approval by providing a plan for the events which would trigger a message, and a suite of text options that may be used for different circumstances (e.g., “thank you” messages for enrolment, key milestones during a long project, and at 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 the participants is recognised in Chapter 3.1, Element 6 of the National Statement as consistent with the ethical principles of respect, beneficence and justice. During the consent process, research teams should advise participants whether, and, if so, in what form, they will receive access to a summary of the outcomes of the research (National Statement 3.1.34). They should also inform participants when this information is likely to be made available (3.1.70) and ensure that any outcomes disseminated to participants are provided in language that is clear and understandable to participants (3.1.71).

Sponsors are responsible for communicating trial outcomes with site Primary Investigators, who are then responsible for the contact with participants. For this sequence of events to take place, it is important for sponsors to maintain relationships with site Primary Investigators until a summary of the outcomes are ready for ethics review and distribution, or to develop a plan to communicate these outcomes to participants after they have closed the site. If a researcher seeks to close a project prior to distribution of a plain language summary of the project outcomes, ethics review bodies should question them about their dissemination plans.

# Conclusion

The CT:IQ and VCCC Alliance Beyond the Form Project has identified a strong demand from participants and regulatory bodies for more meaningful and timely ongoing communication extending beyond the recruitment and consenting phases. However, review of increased communication presents a risk of creating perceived and actual increased administrative burden on ethics review bodies and research staff. Therefore, without practical implementation strategies, there is genuine concern that the intentions of the regulatory bodies may fail to translate effectively into practice. To mitigate this risk, careful interpretation of the available guidance and utilisation of solutions such as communication plans and templates could help streamline processes and reduce administrative load, ensuring that regulations are adhered to without overwhelming research teams or ethics review bodies.

# Appendix 1: Checklist for ethics reviewers

When reviewing the submitted documents, 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 in the trial, use of interpreters, and/or use of support people)
   2. Medium (e.g. email vs SMS text information)
   3. Frequency (e.g. frequency of reminders or updates)
   4. The option to include support people in communications.
4. 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.
5. 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 detail any materials that will be provided to participants during the study, such as expressions of gratitude, individual results, educational health literacy materials or project updates or outcomes.

1. Will these materials require additional review as amendments? This may be required if the study 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 receive these results?