

What is CTRL?

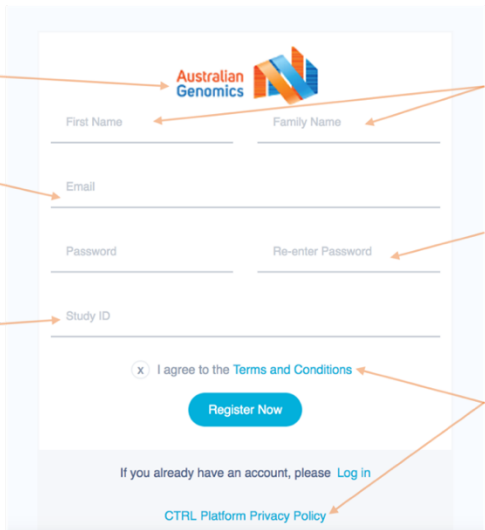
CTRL is an online consent and engagement web application developed by Australian Genomics and inspired by the concept of dynamic consent. CTRL differs to traditional paper-based consent forms in that it is delivered online, and the information can be presented in more flexible ways: for example, in the form of videos and infographics. Research participants can login and update or change their preferences about data sharing at any time. CTRL has been used as a consent option for Australian Genomics flagships and was modified to be used as the consent mechanism for the national reproductive carrier screening study Makenzie's Mission. CTRL has undergone recent upgrades and is now freely available to be adopted by the research community.

Adapting CTRL

CTRL can deliver study information and consent in a different way to traditional paper-based consent forms. Videos, infographics and diagrams can all be embedded into questions or expandable boxes (accordions) to deliver the information to participants in different formats.

CTRL Overview

Registration Page



Logo: Can have the study ID's logo embedded in CTRL with the help of a developer.

First and Last Name: Identifying details that can be used to match a participant to an existing record in another database or recorded as a new login

Email Address: For participants to enter so that they can log back into the portal in the future, participant can be matched up with an existing record on another database or to record for database if first contact with participant.

Password: To be chosen by participant for use when re-logging into platform and can have specifications or requirements placed on it (contains number, upper case, symbol etc).

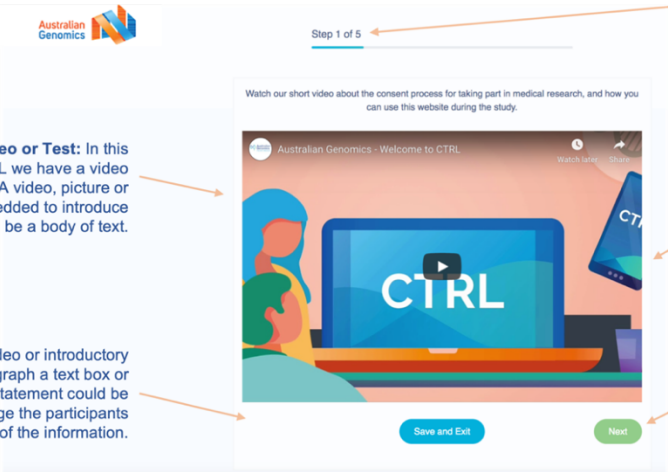
Study ID: Optional component, if you require more than one version of the CTRL platform certain study ID's can trigger different versions. A way to match participants with a number assigned on external database. If this is the first point of contact for a participant CTRL can automatically assign its own ID number. Can place requirements on the study ID in the administration portal.

Hyperlinks: Can hyperlink the terms and conditions or privacy considerations of the study or institute into CTRL.

The registration form includes fields for: First Name, Family Name, Email, Password, Re-enter Password, and Study ID. It also features a checkbox for "I agree to the Terms and Conditions", a "Register Now" button, and links for "Log in" and "CTRL Platform Privacy Policy".

Registration Page: Above is a screenshot of how the CTRL registration page currently looks. Elements like the study ID, password, logo and hyperlinks to privacy policies can be modified for the specific study. If other data capture is required through the registration process a software engineer could add it to the registration page.

Introduction Page



Status Bar: A bar indicating the participants progress through the page appears the first time the participant logs into the platform indicating the number of pages to work through.

Introductory Video or Test: In this instance of CTRL we have a video introducing the study. A video, picture or infographic can be embedded to introduce the study or it can be a body of text.

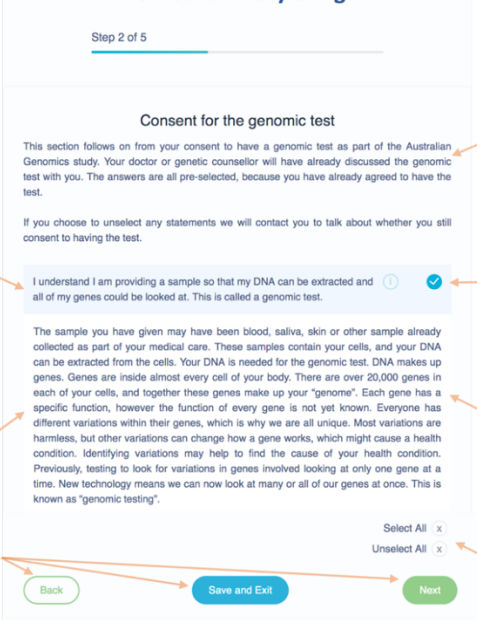
Checked: Below the video or introductory paragraph a text box or acknowledgement statement could be implemented to gauge the participants acknowledgement of the information.

Video Text: The script or information from the video can be hosted below in a accordion box so that if participants would prefer to read the information they can. If the video is embedded from YouTube it can also contain closed captions.

Next Button: When clicked takes participants to the next page.

Introduction Page: Above is one example of how an introduction page to a study could look. In this version of CTRL participants are invited to watch a video about the study which is embedded from YouTube. Embedding a video from YouTube means you could have the additional features such as closed captions. The video script could also be included in a drop down below if the participant would prefer to read it. Otherwise, a text version of the information could be included instead.

Test Consent Style Page



Question or Statement: The questions or statement you require the participant to agree to or acknowledge here have a checkbox style tick, the participant must tick the box otherwise it remains white with a cross. Specific colours can be selected for the ticks.

Media: Different sorts of media such as videos, diagrams, pictures or infographics can be embedded into the accordion boxes with the aid of a developer.

Buttons: The buttons on each page can either navigate to the previous page, the next page or the dashboard where the participant can log out.

Introduction Information: Information introducing the consent form can be added here to describe why consenting is important or a bit more information about the study.

Checkbox: Checkboxes can either be required to tick (the participant cannot move to the next page unless the tick is checked) or an optional 'yes or no' style.

Extra information: If extra information about the question is required it can be added to an accordion box for the participants viewing. If the participant requires the extra information they can click the (i) icon and the information will appear below in an accordion style.

Select/Unselect All: Options to have a 'select or unselect all' button if appropriate for the project.

Consent for a genetic test example: This page is an example of how consent for a genomic test could look on the CTRL portal. In the instance above the page is set up so there is an introduction to the test, the statement or questions that the participant needs to acknowledge and then the option for more information in the expandable accordion section if the participant requires it. All the information presented here can be entered through the administrator portal, so researchers can write their own consent questions or statements. The drop-down box can host media as well as text if suitable for the information to be provided in a picture or infographic format.

There are four different types of questions available for use on CTRL which can be built by using the administration portal:

- A checkbox for participants to tick to either acknowledge or agree to a statement or question.
- Checkbox agreements that must be ticked for the participant to move onto the next page. These can be used for questions that require acknowledgement and if they are not ticked a pop-up box can be triggered to alert the participant of the need to respond to the question.
- Multiple checkboxes to permit participants to select for multiple options at once.
- Multiple choice to permit participants to choose from two or more choices. This option can be used when asking about optional consenting or future data sharing choices or when requesting a simple yes or no response.

Optional Consent Style Page

Step 4 of 5

Preferences about your results

Incidental findings: Because a genomic test looks at many genes at once, a genetic change that is not related to the specific health condition you are being tested for could be found. These incidental findings may be important to know about for your health and for your family as well.

An incidental finding is a genetic change that we know or think is linked with certain health conditions that the testing laboratory comes across accidentally, despite efforts not to look closely at certain genes. It is very uncommon, but you should be aware that it can happen.

Genomic testing services have their own policies about whether they will tell you about incidental findings. If your testing is transferred to a research setting they may identify incidental findings. For those that do return incidental findings, we would like to know your preferences.

I want to know about the genetic change if it is medically actionable (can alter my health management or treatment).

For example, there are some types of cancers that run in families. Sometimes we can find a genetic change that means a family is more likely to develop a cancer throughout their lifetime. If this genetic change is medically actionable, it means these families can reduce that risk through closer surveillance or surgical options.

Introductory Information: Introductory information here might outline that the responses to the choices below are optional and why they're providing optional choices. It might also explain about data sharing options if applicable.

Question or Statement: The questions or statements in this section are worded to elicit optional responses from the participants.

Media: Different sorts of media such as videos, diagrams, pictures or infographics can be embedded into the accordion boxes below the questions.

Multiple Choice: In this optional style consent question the participant can pick a response from three different choices. More or less choices can be added in the administration portal.

Optional Consent Page: The page above is an example of how CTRL can offer optional response questions to participants by implementing either the multiple choice or multiple checkbox question types.

Dynamic consent

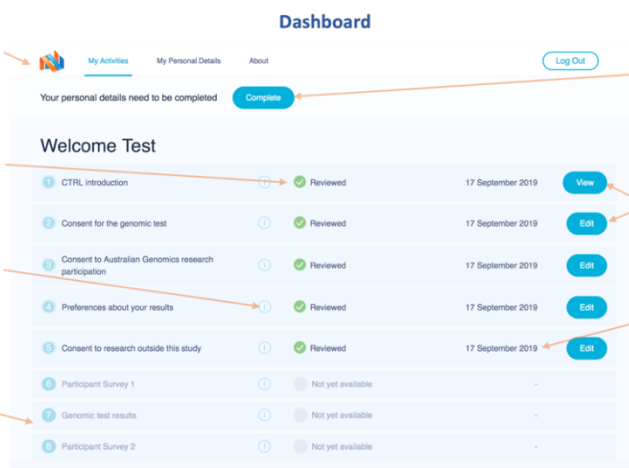
A core design principle of CTRL is that it incorporates the concept of dynamic consent. CTRL is delivered in an online portal format and enables participants to login and review, change or update their preferences about data sharing should they change their mind. In the recent study that used CTRL, the Data Use Ontology codes developed by the Global Alliance for Genomics and Health (<https://github.com/EBISpot/DUO>) were applied in the form of questions to enable participants to make their own preferences about the how their data will be used in the future. The codes were translated into questions that asked participants what sort of organisation they permit to have access to their data, what sort of research they permit their data to be used for and whether they would like to be contacted every time their data was shared. The page exists in the CTRL version available for use and can be adjusted to fit the study or removed if not applicable. With the ability to input multiple choice or multiple checkbox questions optional consent pages can be custom built to specifically fit a project.

Menu Bar: Shortcuts here to a 'personal details' page, a message box that sends an email to the study coordinator or a blog post that can have information or stories about the study.

Reviewed: The green tick indicates that all questions in the page have responses are saved.

(i): Information about each section, such as if the survey or results will be available at a later date can be included in the accordion.

Blurred: Sections of the platform such as surveys and results that exist but are not yet available can be blurred out.



Personal Details: A reminder sits here to request participants to fill in their personal details (address, next of kin, birthday).

View/Edit Buttons: A participant can click this button to view the page and review or update their responses in this section.

Date Reviewed: A date stamp of when the section was last reviewed.

Dashboard: The final page of the portal is the dashboard where participants can review and edit their responses, update their personal details, email the study about any questions and read any extra information the study may want to make available. If the participant decides to login to the portal again they will be directed straight to the dashboard and then can navigate their way around the portal from there.

Integration with an external database

CTRL has the capacity to be integrated with an external database. In the two projects undertaken by Australian Genomics CTRL has been integrated to the external database REDCap using bi-directional API connections that automate push/pull of data between the two software programs. Consent and data sharing preferences are then recorded in REDCap, enabling preferences to be stored alongside other patient record data.

Security & Privacy

The current projects utilising CTRL are hosted on the Murdoch Children's Research Institute (MCRI) server and all data collected through the portal was captured in CTRL and held on the server. The CTRL code is now available for uptake by researchers for their own projects, so the code is deployed on the researcher's own server, ensuring the data captured by the portal is only held by the institute administering the research. CTRL can be hosted on cloud or on-premise infrastructure.

CTRL administrator portal plugin

As part of the upgrades made to CTRL there is now the ability to incorporate an administrator portal via a plugin that means that researchers can enter their own questions and study information into the consent portal. The administration portal allows researchers to build their own questions, create different pages, create compulsory sections and build optional consent questions, thus incorporating a great deal of flexibility. There are also options to hide questions to publish later, select specific colours for question responses and the capacity to download the responses held in CTRL in .csv format. Adding the administrator portal would still require the assistance of a software engineer.

Freely available for uptake

We appreciate that when it comes to consent there is no one size fits all approach. Australian Genomics is offering CTRL as a dynamic consent option for researchers to implement in their own studies. We are excited to see how the portal will be implemented by future projects and the outcomes and experience of researchers and research participants in using CTRL. If you are interested in accessing the CTRL code or would like more information about the portal please visit the CTRL webpage <https://www.australiangenomics.org.au/tools-and-resources/dynamic-consent-and-ctrl/> or get in touch at australian.genomics@mcri.edu.au.