



UTS

IMPACCT
Trials Coordination
Centre

e-Consent Site Manual

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Overview

Purpose

With the advancement of technology to improve efficiencies in clinical trials, changes in trial processes due to social distancing, and changes in patient expectations, the introduction of e-Consent has been gaining momentum.

e-Consent, or electronic consent, is where the process of obtaining participant consent for a clinical trial uses electronic means, and may include passive and interactive systems and webpages, the inclusion of multiple media such as text, graphics, audio and video etc to convey information related to a clinical trial and to document the informed consent.

There are many systems in place for the conduct of obtaining e-Consent, much of which is new within the Australian clinical trials context, ranging from a digital consent form with hand-signed consent through to sophisticated systems integrating multimedia, translation and other technologies.

With the recent changes to the practice of clinical trials instigated by the restrictions imposed by COVID-19, the IMPACCT Trials Coordination Centre (ITCC) at UTS have been investigating the potential of e-Consent within the conduct of UTS sponsored and ITCC coordinated clinical trials. Recent feedback from our recruiting sites regarding the use and capabilities of REDCap has shown us that many of our users would like to see e-Consent adopted in standard practice.

The REDCap Electronic Data Capture (EDC) system is a secure, web-based application for building and managing online surveys and database. It serves as a GCP compliant and validated tool to collect and disseminate research data. The ITCC team propose to set up a process to enable the electronic consent of participants using the REDCap EDC system. This will include developing guidelines and project templates to enable the use of the e-Consent Framework on a study-by-study and site-by-site basis. The ITCC team plan to implement the use of e-Consent for future studies, considering the details of the proposed consent process, the study population, and the appropriateness of the electronic platform for each study overall.

In summary, the process involves the development of an e-Consent project template for each site individually, including the upload of the locally approved, site-specific PICF. Following appropriate training delivered by the ITCC, the tailored e-Consent project will be completely handed over to the Principal Investigator and the delegated site staff to manage. All ITCC staff will be removed from the project by the Principal Investigator after the handover, completely disabling access to ITCC. The site study team are then able to assign their own participants to the e-Consent platform, present the HREC approved PICF, and manage signatures and storage of the signed PICF as per applicable clinical trial regulations. This site managed process enhances the capacity of sites to obtain written consent remotely, thus reducing the number of face-to-face visits and potentially enable more consultation and consideration time for participants during this critical process.

If you have any questions that are not answered by the resources included in this manual, please contact the email addresses below, or refer to the [Contacts](#) section for details about who to contact for specific queries.



Contact us

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Version control

DATE	VERSION	COMMENTS	WHO
01/04/2022	1.0	Final approved	J Hao



e-Consent Structure in REDCap

Organisational Data Governance Oversight

All processes detailed in this proposal will be carried out in accordance with applicable ICH Good Clinical Practice (GCP) requirements and applicable Australian regulations.

The following constitute the most important sources for GCP-compliant data management in Australia:

- ICH E6 (R2) Good Clinical Practice
- NHMRC National Statement (2007) - Updated in 2018

Additional sources refer to Australian regulations and other recommendations, such as:

- Therapeutic Goods Administration: Australian Clinical Trials Handbook (2018)
- Standard operating procedures for Human Research Ethics Committee (HREC) and Research Governance Office (RGO)
- Privacy Act 1988 and Australian Privacy Principles
- Good Clinical Data Management Practices, version 4
- CDISC Clinical Data Interchange Standards Consortium, Operational Data model (ODM)
- CONSORT documentation for reporting of clinical trials.

Any modification (minor or substantial) needed during the project, is governed by the ITCC standard operating procedures (SOPs) which will also be reviewed and updated to capture the e-Consent process.

REDCap Electronic Data Capture (EDC) System Security

The system security is facilitated at several levels:

- **REDCap EDC server's physical plant**

The REDCap EDC system has been configured for the University of Technology, Sydney (UTS). The REDCap database server is housed in the Intersect Data Centre, UTS. The physical servers are located in protected premises, with remote control surveillance of local alarms. Physical intrusion, smoke, fire, temperature control, and electrical failure are permanently monitored (24h).

- **The REDCap EDC system's disaster-mitigation measures**

There is a Nessus Professional Security scanner (from Tenable) in the Intersect Data Centre, UTS. It performs a monthly automated scan of the UTS REDCap server. The UTS REDCap instance has the following backup policy in place:

Instant snapshots via the OpenStack API: The daily backups have a retention period of 7 days, weekly backups have a retention period of 4 weeks, and the monthly backups have a retention period of 6 months. Therefore, there are up to 17 snapshot backups available at any one point.

REDCap data directory snapshots: The REDCap data directory is a Network File System (NFS) mount set on another instance that takes daily, weekly and monthly backups. The daily backups have a retention period of 7 days, weekly backups have a retention period of 4 weeks, and the monthly backups have a retention period of 6 months. Therefore, there are up to 17 data directory backups available at any one point. Nightly database dumps using MySQL dump onto the mounted NFS storage prior to the backup.

- **Website security technologies**

All services are accessible through a secure internet connection (<https://ds.aaf.edu.au/>), provided by AAF (Australian Access Federation) Discovery Service.



REDCap EDC Data Security

REDCap users can use AAF (Australian Access Federation) to log in to REDCap EDC. ITCC staff at UTS can log in using their university credentials. Site users from non-AAF institutions (e.g. data collectors in hospitals and allied health facilities, health departments and LHDs, etc.) need to request an AAF Virtual Home account to gain access. The data manager from ITCC will submit a ticket to request access for external users. The decision to approve or deny access to this database is recorded and communicated via a REDCap email to the applicant. If the access is approved, the data manager will apply via UTS Service Connect online to the UTS eResearch Team to organise access to REDCap for the applicant. The applicant receives a notification to activate their account via email. Upon account activation, the data manager provides access to the relevant project as per the details on the approved Access Request Form. Access for third parties is valid for up to a maximum of one year. The data manager maintains a list of all users who have access to the database. External researchers are required to store data on firewall-protected file shares with access restricted to relevant project personnel only. This evidence is asked as part of the application for the access process.

Each user is identified by a personal, anonymous pseudonym (user code) supplemented by an individual's password. After five unsuccessful attempts, the system will automatically lock the account for 15 mins. Every 3 months, the operator must change their password; user-chosen passwords cannot include previously used passwords. A system time out will automatically disconnect the user after 30 min of inactivity (this time is calculated by two separate send/receive data from/to the REDCap EDC system) with the scope to limit unauthorised access from a computer left unattended while accessing the REDCap EDC system. Moreover, specific profiles are drawn for each user, resulting in different rights (access blocked, consultation only, reading-writing) on each of the server's functions.

Key questions on REDCap e-consent process

- **What is e-consent?**

Electronic-Consent (e-Consent) is a platform for consenting research participants using a computer-based consent form instead of traditional paper documentation. REDCap now has a feature that implements consent forms through an online survey which can be accessed on a computer, mobile phone, or tablet.

e-Consent in REDCap needs to be set up for each project individually. REDCap offers a digital method to acquire and store participant consent through a new e-Consent Framework and PDF Auto-Archiver. Participants can 'sign' their consent by typing in their name and utilising REDCap's 'Signature' field type on the survey.

The REDCap e-Consent feature allows for the upload of the HREC approved PICF. Participants can view the uploaded PICF, sign the consent form within the electronic platform, and then have their signed form countersigned by the PI. This signature can either be signed electronically and then saved, or the PDF of the participant's signed form can be printed onto paper, then signed and saved via the traditional method.

Over time, it may be possible to add additional features such as links to other information pertinent to the study or consent consideration (such as the trial registration, further information regarding participating in clinical trials, blinding and randomisation process, study website, etc.)

- **How does the e-Consent Framework work?**

The REDCap e-Consent Framework provides standardised tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a 'hard-copy' PDF of the signed form.

The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey-taking process.

1) Before a participant completes the survey, an extra certification page is added to the end of the survey that displays an in-line PDF copy of their survey responses. They will be asked to confirm that all information in the document is correct. Once they confirm all is correct, the survey will be marked as complete. The survey will not be considered complete until they fulfil the certification step.

2) Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository. The consent-specific PDF will have the values of the e-Consent framework options inserted at the bottom of each page in the PDF. These values (i.e., name, date of birth, etc.) are added to the PDF as extra documentation of the identity of the consenting person.



- **How do participants use e-Consent?**

The participant will be provided with a link to a 'survey' within REDCap which will contain the approved PICF form, only those with the link will be able to access the e-Consent instrument. The link will be generated by the site team members.

Participants will open the survey and read through the consent form. When they reach the end of the document, the participant will have the opportunity to fill in their information and sign their name if they agree to participate. The participant will select "Next Page" and a read only copy of the consent will be generated for them to review, download, and/or print. At the end of the consent form (the bottom of the page), the participant will be asked to certify the information provided before submitting it. They will need to select "I certify that all the information in the document above is correct, and I understand that signing this form electronically is the equivalent of signing a physical document." Once this is selected, the participant will be able to submit the survey electronically. The participant will also have the option to download the signed consent form as a PDF. Under certain circumstances, a witness to informed consent is required. The name, date and signature of the witness will also be collected within the form.

It is anticipated that this process will be conducted alongside either telephone or video discussion of the study between the participant and the PI or delegated study team member. The participant will have the opportunity to ask questions, seek clarification and take time to review the study information directly with a study team member. The signing of the PICF can be completed during this discussion or can take place at a later time (using the 'save and return later' function), after consultation with others important to the decision making of the participant.

- **How can the 'signature' process be handled in e-Consent?**

Participants can 'sign' their consent form by typing in their name or by utilising REDCap's 'Signature' field type (i.e., 'wet signature') on the survey. One might also assign PIN numbers to prospective participants to aid in the signature process.

Where are completed PDFs of e-Consent forms stored?

The completed PDF surveys are stored in the File Repository under 'PDF Survey Archive' in REDCap. Files can be downloaded as individual records or bundled in a ZIP file. Only site users with 'Full data set' data export privileges will be able to download the archived files. The e-Consent Framework also records the IP address of the participant. It displays this information in the file repository to help regulate potential duplicate forms from a single IP address.

Documentation of the e-Consent process

The person who obtained consent will also be required to document the entire e-Consent process within the participant's clinical medical record in accordance with GCP and ITCC SOP 4.8 Informed Consent. The reasons for this additional documentation are to:

- inform all other clinicians involved in the clinical management of the participant that the correct procedures for consent are followed, including appreciation of the vulnerable position of the participant; and that consent was provided with full disclosure and full understanding.
- provide evidence of the timeline for participation in the study (i.e. consent is obtained prior to study registration and initiation of study related procedures).
- provide substantiation of the process being a dialogue and sharing of information.
- confirm the process in the event that the Consent Form cannot be located at a future time.

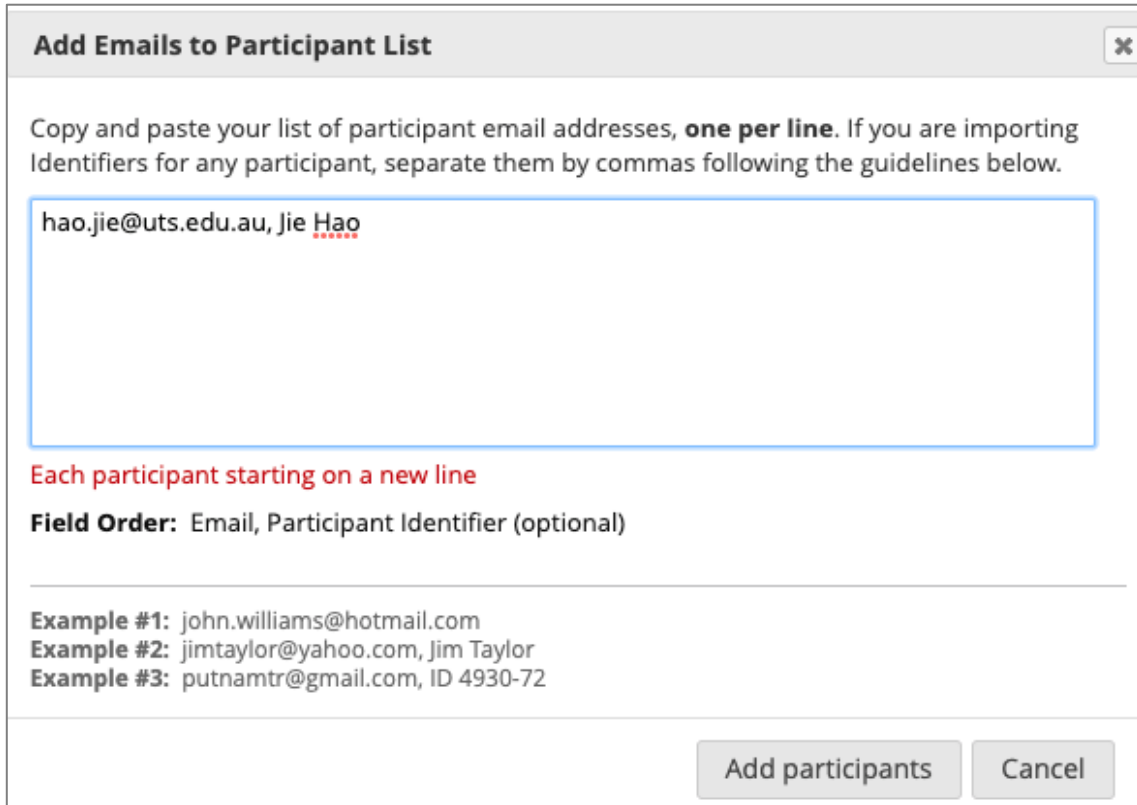


Sites Training Instructions

Using Survey Distribution Tool to send out the e-Consent form to participants

Please go to Survey Distribution Tool\Participant List\Add Participants

Enter the email address of the recipient and if you are using a Participant Identifier, enter a comma and then enter the participant's name (Example: hao.jie@uts.edu.au, Jie Hao).



Add Emails to Participant List

Copy and paste your list of participant email addresses, **one per line**. If you are importing Identifiers for any participant, separate them by commas following the guidelines below.

hao.jie@uts.edu.au, Jie Hao

Each participant starting on a new line

Field Order: Email, Participant Identifier (optional)

Example #1: john.williams@hotmail.com
Example #2: jimtaylor@yahoo.com, Jim Taylor
Example #3: putnamtr@gmail.com, ID 4930-72

Add participants Cancel

If a participant's email address needs to be changed after it has been added to the Participant List, you may simply click on the email address in the list to begin editing it. You may also remove a participant by clicking the remove link next to the participant's name.

Once you have added all your participants, you may compose a survey invitation by clicking on the 'Compose Survey Invitations' icon. This opens a window called 'Send a survey invitation to participants'. You will see a 'Participant List' on your right side. This will provide a list of those who have not responded completely. Select which participants you want to send the invitation to. You may use the drop-down under 'Actions' and select participants who meet specific criteria such as 'Check Not Responded'. On your left side, you can set up a specific time to send a survey email or send it out immediately. The time must be for the time zone Sydney, Australia. If you are in a different city, please adjust the time based on Sydney time accordingly. You can also enable a reminder to re-send the invitation if the participant has not responded by a specified time. Then please fill out your email subject (as ITCC will provide a pre-filled template for your survey message) and click on 'Send invitations' on the bottom right corner.



Send a Survey Invitation to Participants

Info
Survey title: e-Consent Form

When should the emails be sent?
 Immediately
 At specified time: D/M/Y H:M
The time must be for the time zone Australia/Sydney, in which the current time is 05/11/2021 13:59.

Enable reminders
 Re-send invitation as a reminder if participant has not responded by a specified time?

Compose message
From: Display name (optional) hao.jie@uts.edu.au
(select any project user to be the 'Sender')
To: [All participants selected from Participant List]
Subject: Test e-Consent Form Send test email

Paragraph **B** *I* U

Please take this survey.
 You may open the survey in your web browser by clicking the link below:
 [survey-link]
 If the link above does not work, try copying the link below into your web browser:
 [survey-url]
 This link is unique to you and should not be forwarded to others.

NOTE: You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either [survey-link] or [survey-url] in the text or else the participant will not have a way to take the survey.
[How to use Pinging in the survey invitation](#)

- Select a previously sent email to load it in the Compose box -

Send Invitations Cancel

A survey link icon and a QR code icon will be presented next to those 'No Response' icons. It allows you to share the survey to the participant in a different way. QR code can be scanned by a device with an app capable of reading QR codes. Once the QR code is scanned, it will take the participant directly to the survey in a web browser.

Once the survey is sent, the Participant List will show you if the participant has responded, if the invitation was scheduled, if the invitation was sent, and the unique link to the survey invitation. After receiving an email invitation and then completing the survey, the participant's response status in the list will be changed to 'Responded' or 'Partial Response', otherwise their status will remain as 'No Response'. Once a participant has responded, they will not be able to retake the survey.

REDCap

Logged in as hao.jie@uts.edu.au
 Log out
 My Projects
 REDCap Messenger

Project Home and Design

Project Home · Project Setup
 Designer · Dictionary · Codebook
 Project status: Development

Data Collection

Survey Distribution Tools
 - Get a public survey link or build a participant list for inviting respondents

Record Status Dashboard
 - View data collection status of all records

Add / Edit Records
 - Create new records or edit/view existing ones
 Show data collection instruments

Applications

Project Dashboards
 Alerts & Notifications
 Calendar
 Data Exports, Reports, and Stats

e-Consent - internal testing PID 1330

Survey Distribution Tools

Public Survey Link Participant List Survey Invitation Log

The Participant List option allows you to **send a customized email** to anyone in your list and **track who responds to your survey**. It is also possible to identify an individual's survey answers, if desired, by providing an Identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). Note: All survey responses collected are considered anonymous unless you 1) are using Participant Identifiers or 2) have enabled the designated email field for invitations. [More details](#)

Participant List belonging to [Initial survey] "e-Consent Form" Remove all participants

Displaying 1 - 6 of 6 Add participants Compose Survey Invitations Export list

Email	Record	Participant Identifier (optional)	Responded?	Invitation Scheduled?	Invitation Sent?	Link	Survey Access Code and QR Code
[No email listed]			🟢	-	✉️	-	-
[No email listed]			🟡	-	✉️	🔗	📄
1) hao.jie@uts.edu.au			🟡	-	✉️	🔗	📄 remove
2) hao.jie@uts.edu.au		Jessie Hao	🟡	-	✉️	🔗	📄 remove
3) hao.jie@uts.edu.au			🟢	-	✉️	-	-
4) hao.jie@uts.edu.au	12	Jessie Hao	🟡	-	✉️	🔗	📄

If a survey email that has been sent bounces because the email address was entered incorrectly or because the email account is inactive or does not exist, the bounced email will then be redirected back to the site sender to notify them that the recipient did not receive the email.

To keep a clean record of email invitations being sent, the site staff can go to Participant list\Export list, then export all records to an excel spreadsheet.

Useful tips:

- 1) 'Save & Return Later' option is inserted in the survey when the participant needs more time to read the document. This allows respondents to leave the survey and return later.
- 2) When the participant submits a survey, a button will be displayed for the participant to download a PDF file of their responses for the completed survey.

Using Data Entry Form to authorise PI signature

The 'Record Status Dashboard' (under Data Collection) will display e-consent forms by order of Record ID Participant Surname, Participant First Name (For example, 1 HAO, Jie). Auto-numbering is mandatory for the survey project. If no records exist, it will begin with '1.'

The PI or delegate can go to 'Record Status Dashboard' and open an existing record to fill in their information and sign their name (by clicking on 'Edit Response' on the top of the form) if they agree to proceed with an individual participant's consent. Once, the PI or their delegate signs the form and the form status is completed, the e-consent form should be immediately locked by an authorised site person and downloaded. (On the top: Download PDF instrument(s), select this survey with saved data\ send to printer: select "Saved PDF" as the Printer/Destination).

Useful Tips: If the PI or delegate prefer to sign on the paper version of consent form after the participant signs it electronically, the site coordinator can go to the steps demonstrated above on their behalf and print the form for the PI or delegate.

Archive of fully signed consent forms

Downloaded consent forms should be fully signed by both parties (participant signs first, followed by the person who obtained consent). These consent forms will need to be uploaded to the File Repository\PDF Upload New File. The Name/Label as an identifier can be participant name or initials as per site requirements. Once uploaded, these consent forms will be atomically archived in the File Repository\User Files so that the study team with given access right can view and download the form when it is needed.

Useful Tips: The REDCap logging module (Applications\Logging) will list all changes/activities made by all REDCap e-consent project users, including created responses, updated records, lock records and PDF Export with data of users.

