



Technology Use by Participants

Introduction

Participants enrolled in a DCT will likely interact with one or more technologies that facilitate consent, communication, and/or data collection. The processes and materials developed for the use of these technologies in a DCT should enable participant use, support participant access and inclusiveness, and ensure safety and data quality. IRBs/ECs should consider asking the below questions for a DCT trial where participants will use technologies.

Questions for IRBs/ECs to Consider

- Equitable access to the study:
 - How will eligible participants access the technology that is required to participate in the study?
 - Will the participant be expected to provide their own technology (device, software, app, and/or other)?
 - Will the different sources of technology used by different participants impact data quality?
 - If so, will a common technology be provided by the sponsor or investigator?
 - Is the technology accessible for people with disabilities?
 - Have alternative provisions for study participation be made, if necessary?
 - In locations that do not have access to needed infrastructure such as broadband internet, will participants have an alternative option to participate in the study?
 - What costs will the participant incur associated with trial technology?
 - If costs are study-specific costs, will they be paid by the sponsor or investigator?
 - Will reimbursement or an allowance for data plans be provided?
- Device Considerations – see recommendations related to Devices in DCTs, Direct-to-Participant Shipping, and Help Desk documents
- Participant Education, Resources, and Training
 - Technology allows for easy linkages to various types of information (training videos etc). In the study being reviewed, what types of information (e.g., disease or condition, local providers) are available to participants through the technology?
 - Did the IRB review and approve the content of any hyperlinks in the consent and other participant-facing materials?
 - If local providers are engaged, does the IRB/EC have appropriate oversight?



- If the IRB/EC does not have oversight, what risks should be considered and how will they be managed?
- Are participants directed to any promotional materials, advertisements, or commercial resources?
- Have linked websites been included in the IRB protocol for review and approval?
 - Will any of these sites collect, store, or transfer personal information?
- Are study-specific materials (see eConsent tool) provided to participants via remote technologies? If so, does the process include a knowledge check?
- What instructions do participants receive regarding how to use the devices and technology in the study?
- Is the PI or someone from the study team available to participants during the trial if questions or issues arise?
 - Is contact information for the PI or study staff, or a helpdesk resource, (see helpdesk tool) available outside of the technology itself? Note: while this issue is not unique to DCTs, it is often lost in the context of DCTs.
- Are materials easy to read and in plain language?
- Are materials translated into the preferred language of the participant?
 - Will the translations be available via technology and/or paper?
- Will paper copies of the educational resources and training materials be available?

- Privacy/Confidentiality considerations
 - Does the technology include the collection of protected health information (PHI), PII, or sensitive information?
 - Are there measures in place to assure privacy/confidentiality (e.g., end-to-end encryption, secure servers, two-factor authentication)?
 - Is direct contact with participants limited to non-sensitive messages?
 - Is remote removal of all stored information from the technology (e.g., remote wiping of the device) possible in cases of device loss or theft?

- Special Populations – Prisoners
 - Because of limitations on access to devices, the internet, and other systems, DCTs may not be feasible in prisons
 - If a trial participant is sentenced to jail or prison after enrolling in the study, the study team must determine whether it is feasible to continue that person's participation in the trial. If feasible, the IRB/EC should be notified; in certain jurisdictions, the IRB/EC may require re-review of the protocol to ensure conformance with local requirements (e.g., 45 CFR 46 Subpart C in the US.)

- Special Populations – Children
 - If the study involves children, is the technology appropriate for children? Has the parent or guardian approved its use?
 - Are there specific regulations that address studies involving children?



- In the US, if the study involves children ≤ 13 years of age, does the study comply with the [Children's Online Privacy Protection Act of 1998, 15 U.S.C. 6501–6505](#) as amended?
- Are the instructions related to the use of technology age-appropriate?
- Will the child be able to access information using the device or technology other than study-specific materials?
 - Does the parent or guardian understand that information outside of the study can be accessed?
- Are there any devices that will be used by the participant's parent or guardian? Are there any instructions for the participant's parent or guardian regarding any devices being used in the trial?