



Helpdesk Function

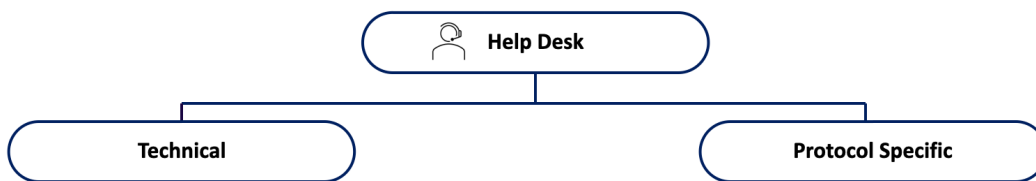
Introduction

A “Helpdesk” function is important for DCTs because it helps individuals respond to, manage, organize, and “troubleshoot” software or hardware issues that arise in technology-enabled tasks. Notably, many participants or their caregivers may not be technically savvy, familiar with the mobile health (mHealth) technology utilized, or even with core functionalities such as access to the internet. Thus, a Helpdesk is typically either a customer service team or a technical system that provides technical support and assistance to users of computer technology. Helpdesks also usually have a ticketing and reporting system for insight into repetitive problems and as a guide to necessary improvements, updates, and ‘bug fixes.’

In addition to software and hardware questions, participants sometimes contact the Helpdesk with questions about the clinical trial, medical questions, symptoms, or other issues. Because it is not the intent of the Helpdesk to answer these questions, participants are referred to the study team by the Helpdesk (see below). However, even in these routine interactions, personal health or other personally identifiable information may be disclosed. Thus, the Helpdesk team must be trained appropriately, and, if the service is provided by a vendor or outside entity, appropriate protections of confidentiality and privacy must be established. Optimally, the vendor will be a Business Associate of the institution conducting the research.

The Helpdesk is NOT the destination for medical advice; all emergencies and medical questions should be referred promptly to appropriate personnel and documented. Participants should be advised that, in general, the Helpdesk will guide the participant to the correct person to answer the question or provide a solution, including being transferred to qualified medical personnel.

Note that it is important to consider site and participant (user) support holistically. While the Helpdesk is the primary touchpoint to support users once an issue has been discovered, there are a variety of methods to empower users and mitigate issues prior to Helpdesk contact. The “best” Helpdesk call is the call that never happens because the system is easy to use, training has been effective, and “self-help” modalities, should a problem arise, are available.



- Typically provided by vendor or sponsor
- Technical help only
- Trained not to provide medical advice
- Access to personal private and health information
- Confidentiality provisions important
- Data retention and storage considerations

- Typically provided by investigator and team
- Medical advice must conform to state licensure requirements
- Confidentiality provisions important
- Data retention and storage considerations
- Helpdesk Documentation Tracker

Considerations for IRB/EC Review

- Based on the type of question, separate people or teams should respond. Helpdesk personnel should have appropriate qualifications, training, and delegation for their role in the study.
- Calls by participants to the Helpdesk should be logged, but no record linking the identity of the caller to the study, condition, or sensitive data should be maintained unless necessary, and if necessary, appropriate procedures to maintain confidentiality and privacy should be in place.
- Call logs, tracking, and reports should be audited for retention of personal health or identical information.
- The IRB/EC can always ask to review the Helpdesk standard operating procedures, personnel training and qualifications, and other materials if needed.

Questions for IRB/ECs to Consider

- Will trial participants have 24/7 access to Helpdesk support?
 - If not, how likely will the lack of assistance cause meaningful risks to patient safety or data quality?
- Will, and how will, the helpdesk staff triage participant questions?
- Will the telephone voice prompt system or operator triage calls be based on the type and nature of the participant's question?
- Does the Helpdesk have scripted questions that are routinely asked?
 - If so, the questions and format should be reviewed.
- Will identifying personal information be maintained securely and only retained when necessary (e.g., for follow-up)?
- Will all helpdesk staff, whether internal or external to the organization, be appropriately trained?
- Will the Helpdesk accommodate underserved and underrepresented populations?
 - Will calls be answered in the preferred language of the caller?
 - If not, how will translation and/or interpreter services be provided?



- Are teletypewriter (TTY) and assistive devices available to accommodate people with disabilities?

Additional Considerations Regarding Helpdesks

When designing a Helpdesk for a trial or if IRBs/ECs have concerns about answers to the above questions, it may be helpful for sponsors and researchers to review these considerations and best practices.

- First contact resolution.
 - The more likely a Helpdesk is to resolve a user's issue in the first contact, the more likely a user is to remain in the study. Complex issues or an ineffective Helpdesk result in user frustration that may drive site friction and patient dropout.
- Study complexity.
 - The more complex a study (number of endpoints, measures and instruments, number of customizations, etc.), the less likely it is that a helpdesk can effectively troubleshoot a user's issue in a timely manner or on first contact.
- Helpdesk training.
 - The effectiveness and regularity with which a helpdesk is trained on both the "product" (technical) and its use in the study, and appropriate referral for study specifics (protocol), the higher likelihood of successful issue resolution.
- Adequate provisions for maintaining the confidentiality and privacy of callers.
 - Provisions for confidentiality and privacy should be established and documented.
 - In the US, if the institution is a HIPAA-covered entity, then it may be appropriate for vendors and call centers to execute a business associate agreement or other contract with the institution.
 - Both the vendor and Helpdesk staff should be trained in:
 - Confidentiality
 - Implicit bias and cultural humility
 - Customer service
 - Accommodating different needs if the participants (e.g., slowing down and simplifying information for people who have difficulty with technology).
 - All records, call logs, and communications should be transferred to the investigator and/or sponsor, stored securely, and retained per record retention policy.
- Sponsors and sites should aim for a positive communication experience for the participant and/or their caregivers.
- Scripted questions should be asked to identify whether the caller has a technical, medical, or protocol-based question.
 - Based on the type of question, separate people or teams should respond
 - Technical staff should be trained not to respond to medical, research, or protocol-specific questions



- If access to personal health or identifiable information, do not maintain a record linking the caller to the study, condition, or sensitive data.
- Call logs, tracking, and reports should be audited for the retention of personal health or identifiable information.
- If there is a medical question or emergency, the caller should be referred to medically responsible personnel, health care providers, or emergency services, as necessary.
 - Medical and professional licensure requirements must be met if medical advice is provided.
- If there is a research or protocol-specific question, qualified research staff should be positioned to answer, familiar with the protocol.
 - Medical and professional licensure may be necessary depending on the advice given.
 - The role of the Helpdesk personnel should be understood. If the Helpdesk personnel are engaged in medical advice or research processes, they should have appropriate qualifications and delegation for the role in the study.
- The investigator and sponsor should be informed about technical issues raised by the participants and should consider whether the technical issues are impacting trial participation, data quality, or execution of the clinical trial protocol.
- Technical issues should be fixed in a timely manner, and the investigator and sponsor may need or wish to review any time delays in issue resolution.
- The Helpdesk should provide a report on issues encountered and how they were resolved.