CHECKLIST FOR INVESTIGATIVE SITES:

Questions to Ask During Budgeting and Contracting

During budgeting and contracting for a clinical trial using mobile technology, investigators may wish to ask the sponsor a variety of questions that are specifically related to the use of that mobile technology, such as the following:

QUESTIONS TO ASK	PRACTICAL EXAMPLES
GENERAL BUDGETING AND CONTRACTING CONSIDERATIONS	
▶ What information is available from pilot testing and/or prior studies to assist us in estimating time and costs associated with the use of mobile technologies in this trial?	▶ Well in advance of trial launch, the sponsor provides information gathered during pilot studies to help facilitate accurate budget preparation.
▶ What flexibility will be built into the budget to allow for unanticipated costs?	▶ Budgets are structured to account for site costs that may arise during the trial due to unanticipated challenges or requirements associated with mobile technologies used.
▶ What will the patient visit schedule be, and what payment structures are available other than per-visit payments?	▶ For a trial in which most site visits are replaced with mobile data collection, alternative payment structures, such as lump sum budgets, are considered.
SITE STAFF TRAINING AND FAMILIARITY CONSIDERATIONS	
▶ How will training of site staff on mobile technologies be conducted, and what will the time requirements be?	▶ Training is planned to include hands-on practice with the mobile technologies, engage all site staff who will be regularly working with the relevant mobile technologies, and account for diverse learning styles. ▶ Strategies to enhance participant adherence to the use of mobile technologies are reviewed with relevant site staff as part of the training.

QUESTIONS TO ASK	PRACTICAL EXAMPLES
▶ If staff members have already been trained on the mobile technologies in a prior study, will they be required to repeat the trainings?	▶ Training is focused on study-specific elements rather than fully repeating training that has already been completed.
▶ What will the role of site staff be in providing technical support for study participants?	▶ Site staff serve as the initial point of contact for trial participants who have technical issues. ▶ Requirements for site staff to conduct initial troubleshooting are clearly delineated, along with availability of external technical support when necessary to address issues.
▶ What other technical support will be available to participants?	▶ Technical support personnel who are external to the site are trained in unique considerations for the patient population, with hours of availability that meet participant needs.
SITE SYSTEMS AND WORKFLOW CONSIDERATIONS	
▶ What responsibilities related to mobile technologies will site staff have for data entry, and clinical event identification and follow-up?	▶ Expectations related to data management, monitoring participant health and safety data in real time, response time requirements, and responsibilities with respect to adverse events reported or detected through mobile technologies are identified and reviewed.
▶ How much time and space will be required for consenting and training procedures?	▶ Time and space requirements associated with training and consenting patients on mobile technologies are identified based on piloting and/or prior experience. ▶ Any additional time requirements for site staff to monitor participant adherence and to remind and re-educate participants when necessary are also identified and reviewed.
▶ How many devices will be available to our site throughout the study, and how will technology malfunctions and loss be handled?	▶ Device availability is discussed and considered in order to safeguard against the possibility that having an inadequate number of devices will hamper enrollment ▶ Plans for monitoring and responding to technology loss or malfunction are in place before enrollment begins.
▶ What back-up systems are in place in the event of technology failure?	▶ For all time sensitive data collection, contingency plans are in place to collect data via a paper back-up form that has been translated and approved by the IRB/EC.
▶ What other workflow considerations should we be aware of?	▶ Expectations or requirements related to pilot testing, support developing training materials, and similar activities beyond those indicated in the study protocol are clearly delineated.

QUESTIONS TO ASK	PRACTICAL EXAMPLES
PHYSICAL AND IT INFRASTRUCTURE CONSIDERATIONS	
▶ What physical and IT requirements associated with the mobile technologies will we need to plan for?	▶ Requirements are identified related to physical space needed to store and charge mobile technologies, as well as any Wi-Fi coverage and speed requirements at the site. ▶ For any remote communication between sites and patients, both technical requirements and privacy requirements are identified and considered against site infrastructure.
▶ Does the mobile technology require the use of any third-party hardware or software?	▶ Any requirements to use third-party hardware or software (e.g., to activate mobile technologies used in the study) are identified and considered against local IT restrictions and requirements. ▶ Options for meeting site and study IT requirements are identified (e.g., options to install required software on site computers, or for sponsor to provide compatible computers).
▶ What technical support will be available to our site?	▶ To enable efficient issue escalation and resolution in the event of technical challenges, processes are established for the site to communicate with the technology vendor and/or manufacturer directly.
PATIENT POPULATION CONSIDERATIONS	
▶ What feasibility testing has been completed with patients and sites to ensure the mobile technology meets patient needs, fulfills study requirements, and will be used as intended?	▶ The sponsor describes evaluations of acceptability, usability and tolerability conducted that informed selection of mobile technologies that are acceptably easy to learn, simple and convenient to use, and physically comfortable.
▶ What patient communication plans have been developed, and what will the site's role be?	▶ The sponsor discusses plans for communicating with participants and potential participants about privacy and confidentiality, setting expectations about access to outcomes data generated by mobile technologies during the trial, and ensuring participants remain engaged and connected.
GEOGRAPHIC CONSIDERATIONS	
▶ In what languages and time zones will technical support be provided?	▶ Sites are informed of languages in which instruction manuals for mobile technologies and live tech support will be available, as well as the hours of availability of tech support in the local time zone.