Developing a Remote Clinical Research Protocol: Lessons Learned in the Age of Covid-19

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Introduction: The COVID-19 pandemic resulted in widespread shutdown of clinical research activities. Six studies from a P30 Center developed and implemented innovative strategies to minimize COVID-19 exposure to their high-risk study participants while maintaining the integrity of research projects. Modifications to transition to remote data collection, include clinical data (height, weight, blood pressure), biologic samples (blood, saliva, rectal swabs), and a battery of questionnaires.

Methods: Data collection was adapted for each study to enable self-collection at home according to study purpose and progress. All remote collection protocols were IRB approved. Studies employed remote informed consent by telephone or REDCap or the consent process was streamlined to reduce contact. Supplies and detailed instructions were sent to participants for remote data collection. Questionnaires were completed through REDCap or on paper. Participants self-collected biological samples via dried blood spots (DBS) on filter paper (one study) or Mitra microsampling (two studies), saliva collection tubes, and rectal swabs or fecal samples. Cognitive testing for one pilot was conducted over video conference. Collected data were returned using a pre-paid, addressed return shipping box or picked up by a masked research coordinator. Validation testing of DBS against stored venous samples was implemented for high throughput methods.

Progress to date on development of project: Study PIs worked together to create similar protocols. Three studies transitioned from in-person to semi-remote data collection; one launched recruitment of a nearly completely remote protocol; and two studies developed an entirely remote protocol. Data collection is ongoing. Thus far, 18 participants across all six studies have participated remotely. Satisfaction is high, with 100% of participants from one study responding they would be very likely to participate in future studies conducted from their own home. Important considerations for successful implementation of a remote data collection protocol include the need for clear communication to ensure protocol fidelity, high accessibility for participant questions, and sufficient funds to account for postage and supplies. Even beyond the pandemic, remote protocols offer a participant-centered approach to clinical research.