Research Continuity and Operations During a Global Pandemic: Remote Work, Security, and Patient Safety

Linden Lalley-Chareczko, MA; Emily Hiserodt, MPH; Gerald van Buskirk, BS; Karam Mounzer, MD
Philadelphia FIGHT Community Health Centers

Background

- First case of SARS-coV-2 [COVID-19] identified in Philadelphia on March 10th, 2020
- On March 13th, 2020, all non-essential research appointments were cancelled - Research staff advised to make alternative arrangements for data collection, laboratory procedures, medication dispensation, etc.
- New clinical research, not addressing COVID-19 or providing life-sustaining treatment, was put on hold.

Major Questions

- What is the safest way to manage AEs?
- What about patients receiving study medications?
- What if my patient becomes COVID-19+?
- What are best practices for study monitoring?

Better Integration of Technology into Clinical Research is Key

Telemedicine and Remote Testing

Leverage local clinic software ensuring HIPAA compliance
Hybrid remote/on-site visits
Guided self-swab HIV and rectal STI testing

Secure Shipping

Obtain verbal consent prior to each shipment
Consistent temperature monitoring
Supplying bottle return envelopes

Digital Consent & e-Forms

REDCap and DocuSign
Both allow for upload of original document without alterations and secure document storage
Copies available to participants (op-out)

COVID Screening

All patients verbally screened for COVID-19 symptoms
On-site and community PCR testing available
COVID-19+ reported as “special trial circumstance”
ICF addenda required

These changes are here to stay! Including all technological resources better serves the community and opens opportunities for education.