Research Professionals Network Workshop Series

REMOTE STUDY VISITS

BU Clinical & Translational Science Institute (CTSI)

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Objectives:

Alexa Bragg — Boston University School of Medicine

- Provide a brief overview of clinical trial research during the COVID-19 pandemic.
- Identifying best practices for conducting research remotely.

Patti Lutton — University of Vermont (UVM) and UVM Medical Center

- Provide example of Hybrid Screening Model: benefits/challenges.
- Discuss changes in our visit model during the pandemic as compared to pre-pandemic.

Cindy Montero — University of Florida College of Medicine

- Provide example of an inpatient drug clinical trial during the pandemic: benefits/challenges.
- Discuss changes in our visit model during the pandemic as compared to pre-pandemic.

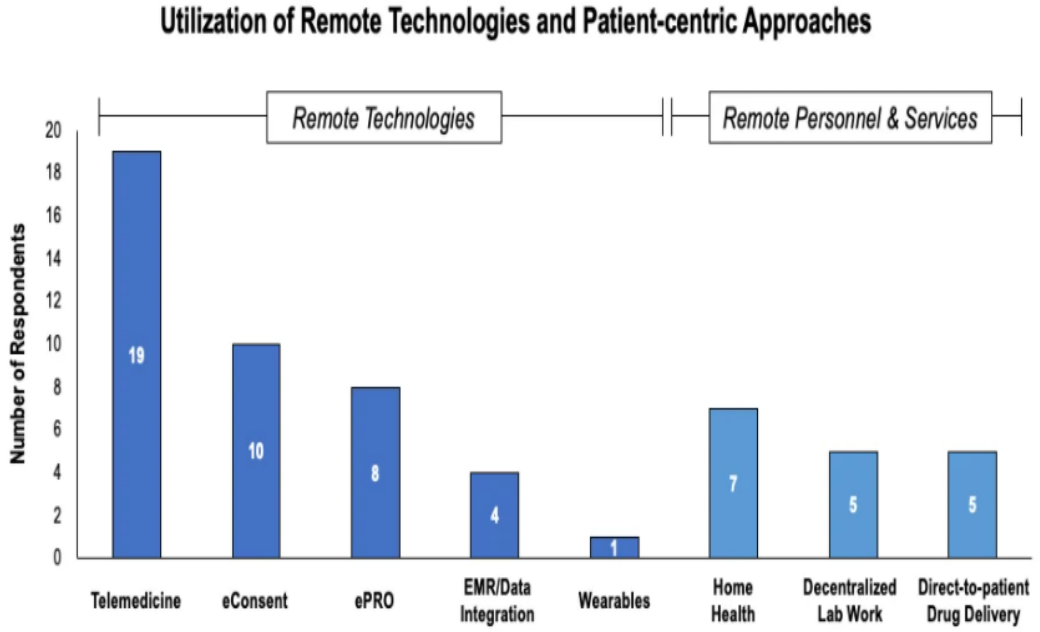
COVID-19 Pandemic: Pivot to Remote Study Visits

THE WALL STREET JOURNAL.

Coronavirus Pandemic Delays Testing of New Drugs

Pharmaceutical companies adjust to patients skipping treatments and hospitals shifting focus to coronavirus

FDA Commissioner Stephen Hahn said the agency will test chloroquine, an antimalarial drug, as a coronavirus treatment. The drug could serve as an intermediate therapy before a vaccine becomes available. Photo: Evan Vucci/Associated Press



https://www.appliedclinicaltrialsonline.com/view/covid-19-and-its-impact-on-the-future-of-clinical-trial-execution

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Boston University School of Medicine and Boston Medical Center

June 25, 2020: Institutional Officials at Boston University Medical Campus and Boston Medical Center released plans for resuming in-person research interactions.

Studies that do not need approval to resume: interactions are 100% remote (including sponsored-studies).

Studies that need approval to resume: Non-COVID studies that wish to resume in-person interactions with a member of the study team. Must complete: (1) Research Recovery Plan, (2) Research Personnel Template (3) Resuming In-Person Subject Interactions

Institutional Links: FAQs: Impact of COVID-19 on Human Subjects Research | Institutional Review Board (bu.edu)

Overview/Factsheet: High_Level_Research_Restart.pdf (bmc.org)

CRTimes article ON Planning Studies to Minimize Visits to BMC/MU Med Campus: https://wwwapp.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=780

University of Vermont (UVM) and UVM Medical Center

As of February 1, 2021 transition from a Level 4 to a Level 3.

Research Activity Level	Laboratory Staffing/ Activities	Fieldwork	Allowable Fieldwork related travel	Allowable Overnight Fieldwork Accommodation	Face-to-face direct contact research with human subjects	Undergrad Participation	Research Building Access	In-person Lab Meetings
Research 3	Wet and dry lab activities by faculty/ staff, grad/post-doc, medical students, approved undergrads only	Activities restricted to fulfilling core[4] project objectives	Only in-state travel. Participation restricted to minimal field crews who can travel in separate vehicles or vehicles (boats) where adequate physical distancing is possible	Only if team members can isolate in separate accommodations or are part of an existing "family unit."	In clinical setting, PPE protocols must align with institutional requirements; Incidental or low risk physical contact only; where remote data collection is possible, it should be used. Face-to-face with groups is limited to 3 participants and the researcher and only where social distancing is possible.	Approved, project "critical" UVM undergraduate student assistants; no non-UVM students or volunteers. No UVM students prevented from attending class/activities due to possible COVID exposure[5]	No building transit / pass through, UVM-based colleagues with prior approval	Per approved laboratory plans

Public Institutional Link: COVID-19 Information for RPO | Research Protections Office | The University of Vermont (uvm.edu)

Internal links: https://commons.med.uvm.edu/dean/comclntril/SitePages/COVID-19%20Information%20for%20Researchers.aspx

https://fahc.sharepoint.com/teams/Coronavirus

University of Florida and UF Health

A three-stage framework for resuming all research activities throughout the University of Florida during the next phases of the COVID-19 pandemic.

Institutional links:

https://clinicalresearch.ctsi.ufl.edu/covid-19/

http://irb.ufl.edu/index/covid-19-resources.html

https://coronavirus.ufhealth.org/

UF Clinical Research Resumption Plan

Research Location	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
Patient Care Areas - Outpatient					
Allowed Research	▪ Therapeutic (Life Threatening) ▪ COVID-19	▪ Therapeutic (All) ▪ COVID -19	▪ Interventional (All) ▪ Diagnostic/Screening ▪ COVID -19	▪ Interventional (All) ▪ Observational (All) ▪ COVID -19	▪ Gradual return to all activities
Allowed Research Visits	▪ Life Threatening ▪ COVID-19	▪ Concurrent with Clinical	▪ Research-Only	▪ Site Initiation ▪ Monitoring	▪ All
PPE Requirements*	▪ At minimum, research staff must wear Surgical Masks, Eye Protection ▪ In addition, follow all current requirements/recommendations in PPE section of *Patient Care Clinical Guidance* on UF Health Bridge				
Max. Occupancy Limits	▪ Social Distancing	▪ Social Distancing	▪ Social Distancing	▪ Social Distancing	▪ TBD
Patient Care Areas- Inpatient					
Allowed Research	▪ Therapeutic (Life Threatening) ▪ COVID -19	▪ Therapeutic (All) ▪ COVID -19	▪ Interventional (All) ▪ Diagnostic/Screening ▪ COVID -19	▪ Interventional (All) ▪ Observational (All) ▪ COVID -19	▪ Gradual return to all activities
Allowed Research Visits	▪ Life Threatening ▪ COVID-19	▪ Concurrent with Clinical	▪ Research-Only	▪ Site Initiation ▪ Monitoring	▪ All
PPE Requirements*	▪ At minimum, research staff must wear Surgical Masks, Eye Protection ▪ In addition, follow all current requirements/recommendations in PPE section of *Patient Care Clinical Guidance* on UF Health Bridge				
Max. Occupancy Limits	▪ Social Distancing	▪ Social Distancing	▪ Social Distancing	▪ Social Distancing	▪ TBD
Patient Care Areas - Research Locations (e.g. Clinical Research Center, CTRB, AMRIS, Institute of Aging, CERB)					
Allowed Research	▪ Therapeutic (Life Threatening) ▪ COVID -19	▪ Therapeutic (Life Threatening) ▪ COVID -19	▪ Interventional (All) ▪ Diagnostic/Screening ▪ COVID -19	▪ Interventional (All) ▪ Observational (All) ▪ COVID -19	▪ Gradual return to all activities
Allowed Research Visits	▪ Life Threatening; COVID-19	▪ Life Threatening; COVID-19	▪ Research-Only	▪ Site Initiation ▪ Monitoring	▪ All
PPE Requirements*	▪ At minimum, research staff must wear Surgical Masks, Eye Protection ▪ In addition, follow all current requirements/recommendations in PPE section of *Patient Care Clinical Guidance* on UF Health Bridge				
Max. Occupancy Limits	▪ Social Distancing	▪ Social Distancing	▪ Social Distancing	▪ Social Distancing	▪ TBD
Community-Based Research					
Allowed Research	▪ COVID Screening ▪ Remote Only	▪ COVID Screening ▪ Remote Only	▪ Interventional	▪ Interventional ▪ Observational	▪ Gradual return to all activities
Allowed Research Visits	▪ None	▪ None	▪ Research-Only	▪ Site Initiation ▪ Monitoring	▪ All
PPE Requirements *	▪ Not applicable	▪ Not Applicable	▪ Surgical Masks	▪ Cloth Masks	▪ TBD
Max. Occupancy Limits	▪ Not applicable	▪ Not Applicable	▪ TBD	▪ TBD	▪ TBD

Common Challenges and Concerns:

- Elimination/reduction of face-to-face study visits
- Primary outcome assessments
- Enrollment of study participants
- Shift to telemedicine platforms
- Collection of labs offsite
- Change to drug delivery
- Delayed study-start up

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Virtual Study Activities

- **Recruitment, Pre-Screening, and Consent**: via video, phone, email
- **Safety assessment**: abbreviated exams
- **Delivery of Intervention**: telemedicine, at-home delivery of investigational product (FedEx), home infusion service
- **Data Collection**: via phone, video, off-site labs

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Delivery of the Intervention: Telehealth

Telehealth is not a new technology; rather it was relatively underused prior to the 2020 COVID-19 pandemic

Advantages:

(+) provides continuity of care

(+) comparable to face-to-face interaction

(+) reduces frictional distance for study participations to travel

Considerations:

(-) Privacy limitations

(-) Access to technological devices

(-) Capability of using technology

(-) Cultural acceptance of conducting virtual visits

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Case Example #1: Women in Control 2.0 Study

5-year Randomized Controlled Trial funded by the National Institute of Diabetes and Digestive and Kidney Diseases.

Compare the effectiveness of diabetes medical group visits conducted in the **virtual world** (Second Life) versus a **face-to-face** format for minority women with uncontrolled diabetes mellitus.

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HSR Considerations during COVID-19

- RESEARCHERS SHOULD CONSIDER THE EMOTIONAL/AFFECTIVE ENVIRONMENT OF ENROLLED PARTICIPANTS.

- RESEARCHERS SHOULD CONSIDER HOW REMOTE APPROACHES MAY CREATE OPPORTUNITIES AND BARRIERS TO DIVERSITY, EQUITY, AND INCLUSION.

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Case Study:

NIH-funded socio-behavioral study

You are a Research Coordinator at Boston Medical Center. The PI of your team received a notification of award grant from the National Institute of Diabetes, Digestive, and Kidney Diseases to conduct a pilot feasibility trial. The pilot portion of the study aims to evaluate the feasibility and efficacy of a diabetes self-management education and support (DSME/S) intervention hosted in the virtual environment. This study offers weekly synchronous DSME/S classes in an online platform.

Study Design: a single group, pre-to-post measure design. Weekly 1-hour DSME/S classes (facilitated by nurse practitioner) will be held during the daytime and evening to allow participants flexibility for attendance. Participants' perceived virtual environment usability, usefulness, and self-efficacy is assessed using validated survey measures (0, 3, and 6-months). Metabolic indicators (HbA1c, BP, BMI) are also collected at the aforementioned time points.

What are key considerations in conducting study visits remotely?

Recruitment? Screening and Consent? Enrollment and Group Visit? Data Collection?

Useful Links and Literature:

Doshi A., Platt Y., Dressen J.R. Keep calm and log on: telemedicine for COVID-19 pandemic response. J Hosp Med. 2020;15:301–304. http://www.ncbi.nlm.nih.gov/pubmed/32379036 doi:10.12788/jhm.3419

Marhefka S, Lockhart E, Turner D. Achieve Research Continuity During Social Distancing by Rapidly Implementing Individual and Group Videoconferencing with Participants: Key Considerations, Best Practices, and Protocols. *AIDS Behav*. 2020;24(7):1983-1989. doi:10.1007/s10461-020-02837-x

Collecting Qualitative Data. (2017). In V. Braun, V. Clarke, & D. Gray (Eds.), *Collecting Qualitative Data: A Practical Guide to Textual, Media and Virtual Techniques*. Cambridge: Cambridge University Press.

Daniels, N., Gillen, P., Casson, K., & Wilson, I. (2019). STEER: Factors to consider when designingonline focus groups using audiovisual technology in health research. International Journal of Qualitative

Conducting a High Volume Research Study During a Pandemic

A Hybrid Model

Patricia Lutton, CCRP
University of Vermont
Larner College of Medicine

RPN – 21Feb2021

The University of Vermont
LARNER COLLEGE OF MEDICINE

Procedure Changes – During COVID

Pre-COVID	During COVID
Screen Visit including education/consent all in-person	Pre-ICF educational contact prior to ICF
Volunteer waits in waiting room	Volunteers calls from vehicle upon arrival/escorted directly to exam room/smaller groups
Volunteers transition from station-to-station for each study step – study team member performs specific role	Volunteer remains in one room for entire visit/one study team member performs multiple study visit tasks within scope of practice
No social distancing concerns/large dosing groups	Social Distancing of volunteers and study staff – smaller dosing groups/appointments distanced
Volunteer could be accompanied by a guest	Volunteer not allowed to bring guests
Standard infection control procedures	More stringent infection control procedures between volunteers – including masks for staff/volunteers
Standard PPE	Additional PPE/ isolated room for illness visits
No COVID/Illness pre-screen required	COVID-19 Symptom Checklist/at door screening

The Goal and the Challenge:

- High Volume Study - approximately 3,000 prospective volunteers (very rapid response).
- Short recruitment period: Recruitment window approximately 8 weeks
- Goal: Enroll approximately 250 participants in 8-10 week period.
- Informed Consent - same day as study procedure.
- What did we do and why?

A Hybrid Screening Process

- RedCAP Online pre-screen.
  - Thousands of responses in RedCap in a short timeframe.
  - Categorized based on risk factors
  - reduce # of ineligible people
  - Communication between staff in a ZOOM kind of world!
- Remote Pre-informed consent educational discussion.
  - Improved space utilization
  - Reduced infectivity risk– reduced # of in-person screen appointments
  - Volunteer Education and Time
  - Fewer in-clinic screen fails or volunteers declining participation in clinic.

Contact/Send Read-Only Consent

IRB-approved Read-Only Consent

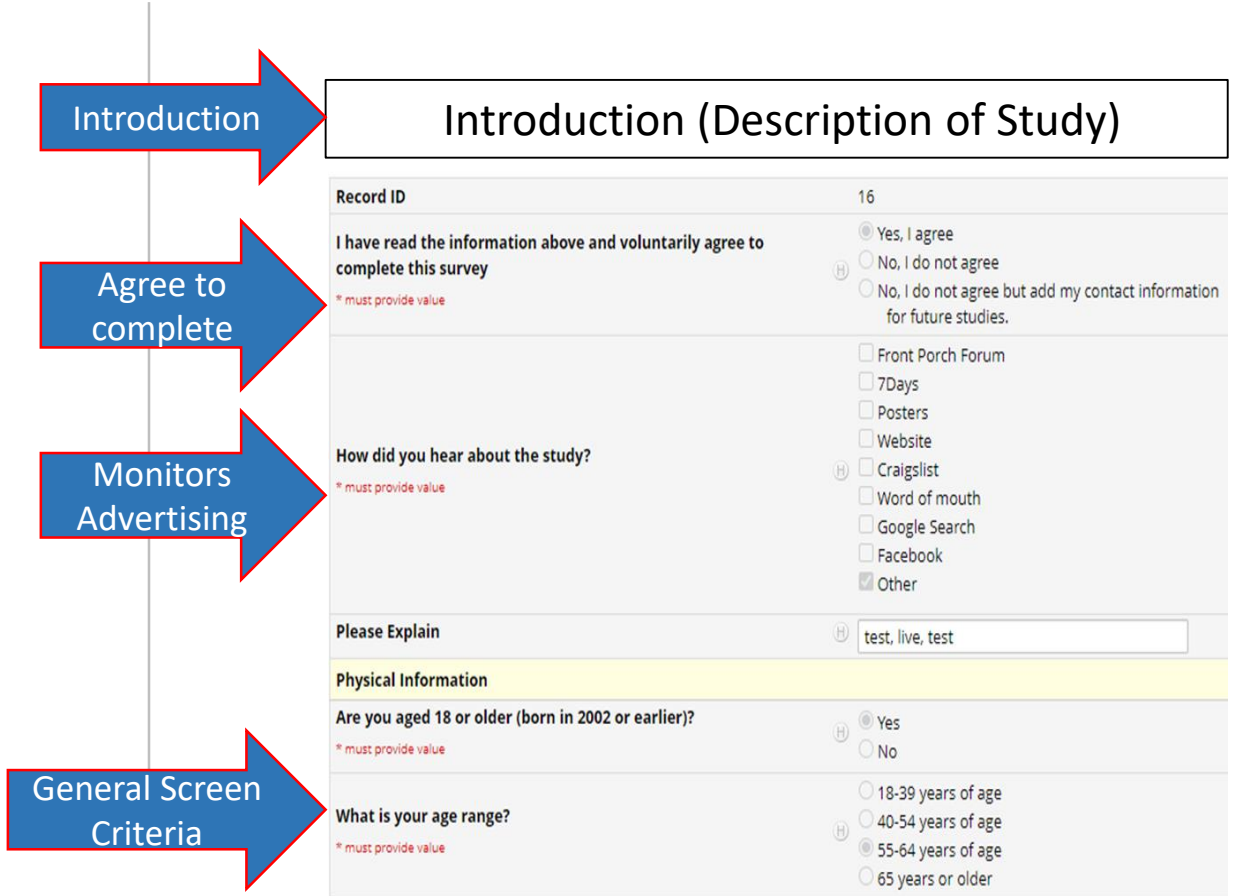
- ✓ Volunteer education
- ✓ Volunteer time
- ✓ Enhanced decision-making process
- ✓ Reduced in-person clinic time/infectivity control

Pre-ICF Remote Discussion

- Prospective volunteer contacted at scheduled time (every 30 minutes).
- Reviewed Consent Components/Answered questions
  - ✓ Volunteer education
  - ✓ Volunteer time
  - ✓ Reduced in-person clinic time/infectivity control
  - ✓ Assessment of understanding
  - ✓ Another Catch-point for those who decline/ineligible

Online Pre-screen survey Example

- RedCAP pre-screen survey completed by prospective volunteer
- Reviewed by PI or designee
- If meets general pre-screen eligibility, contacted by study team member



Contact Reports

Tracking Contacts (can review by date or all contacts)

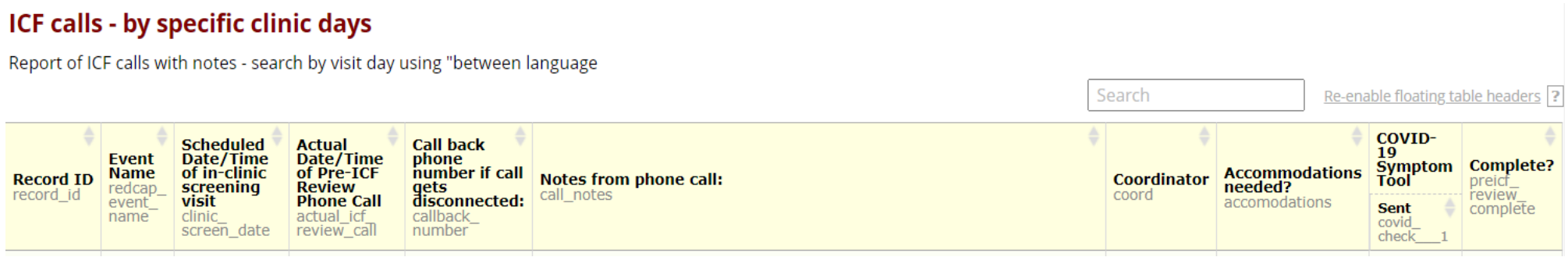
Pre-screen ICF Calls Report - by date

Report of ICF calls with notes - search by visit day using "between language

Search | Re-enable floating table headers ?

Record ID record_id	Event Name redcap_event_name	Actual Date/Time of Pre-ICF Review Phone Call actual_icf_review_call	Scheduled Date/Time of in-clinic screening visit clinic_screen_date	Notes from phone call: call_notes	Call back phone number if call gets disconnected: callback_number	Coordinator coord	Accommodations needed? accomodations	Complete? preicf_review_complete

Study Team/Clinician Review Pre-ICF Contact on Day of Appointment



ICF calls - by specific clinic days

Report of ICF calls with notes - search by visit day using "between language

Search | Re-enable floating table headers ?

Record ID record_id	Event Name redcap_event_name	Scheduled Date/Time of in-clinic screening visit clinic_screen_date	Actual Date/Time of Pre-ICF Review Phone Call actual_icf_review_call	Call back phone number if call gets disconnected: callback_number	Notes from phone call: call_notes	Coordinator coord	Accommodations needed? accomodations	COVID-19 Symptom Tool Sent covid_check___1	Complete? preicf_review_complete

Other Modifications During the Pandemic

Infection Control Practices (Physical Distance, PPE, Clinic Lay-out)

- ✓ Volunteers called from their vehicle upon arrival at study site.
- ✓ Volunteers escorted to exam room – stayed in room for entire visit.
- ✓ One Staff Member performed multiple tasks.
- ✓ Designated Room/Entrance for illness visits.
- ✓ Appropriate PPE worn by study team members and study participants.

Benefits

- Provided prospective volunteers additional time to read ICF, discuss with peers, prepare questions PRIOR to in-person ICF appointment.
- More efficient use of clinical space/duration of in-person contact reduced.
- If participant declined participation at the Pre-ICF remote contact, appointment time/clinic space available for other study volunteers
- Alerted Clinic Team to Volunteer Questions Prior to In-person Visit

Challenges

- Prospective Volunteer had not always read the informed consent.
- Prospective Volunteer not reachable at scheduled time -contacted coordinator during another volunteer appointment.
- Prospective Volunteer had more questions than scheduled time allowed.
- Not all volunteers had access to internet (telephone/teletriage script).

It Takes a Village….

The Team:

- Lisa Smith, RN
- Mary Claire Walsh, PA
- Sunday Whipkey
- Ashley Miles
- Research Nurses and assistants, Clinicians, and Laboratory Technicians

This research study was a team effort. It took everyone working together for the success of this high-volume, fast-paced research study.

Case Study:

You are a research coordinator. You PI/site has been selected to conduct a Phase III study to evaluate a new COVID-19 vaccine for efficacy and durability. The enrollment goal is to enroll 300 people in an 8 week enrollment period. Community response to the trial is overwhelming with approximately 3,000 interest potential volunteers for 300 available spots.

Study Design: Randomized clinical trial, vaccine vs. placebo - 2:1 ratio. Weekly visits and additional illness visits for those volunteers who develop COVID-like symptoms during study participation.

What are key considerations in conducting study visits remotely? In terms of ….

Recruitment?

Screening and Consent?

Enrollment and Group Visit?

Mitigation strategies for infection prevention?

Data Collection?

UF Emergency Medicine Research

Conducting Remote Study Visits

Cindy Montero MS, CCRC
Lead Clinical Research Coordinator

UFHealth
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Who we are and what we do!

- Team of 12 Coordinators and research assistants
- 24/7 Research Infrastructure working in Emergency Department (ED) at UF
- Recruit for clinical trials in the ED and follow patients throughout the hospital
- Specialties include cardiac arrest, TBI, and drug intervention clinical trials
- BSL2+ lab and workspace in the Trauma bay of the ED

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COVID-19 Changed Things…….

How do we continue research during a pandemic?

- Switch to Remote
  - Regulatory
  - Patient Interaction
  - Study Visits
  - Sample Collection
  - Follow Up

. **How do you prepare your staff to go digital?**

Epic

Pulse Secure

Trello

Microsoft Teams

REDCap

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A New Challenge Arises…….

- **Launching new inpatient interventional drug clinical trials enrolling:**
  - **COVID-19 Positive Participants**
    - Mostly on supplemental oxygen
    - Anxious
    - Mostly between the ages of 30-95yo
    - Inpatient/Outpatient visits
  - **Challenges:**
    - Digital Enrollment (Zoom, Phone)
    - Remote Study Visits
    - Remote Rounding
    - Specimen Collections
    - Protection of staff
    - Out of hospital Follow up

Environmental Health & Safety

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Types of Study Visits

Visit Type	Collection Format
Surveys, CRFs, Diaries , etc.	Paper Versus Digital
Sample Collection	In Person/ Alternatives
AEs and SAEs	In person/ remote

- ***How do you conduct study visits without face to face interaction?***
- **How do you round on patients who are inpatient during COVID-19?**
- **How to navigate required in person study visits during COVID-19?**

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Remote Study Visits

Surveys:

- Distribution can include:
  - Email
  - Phone
  - Zoom
  - IPAD
    - Cleaning Precautions

CRFs:

- Collect Data from EMR
- Coordinate Vitals and Labs
- Medications can be Tricky

Sample Collection:

- Create SOP with EHS
- Coordinate with Nursing
- Follow Best Practices

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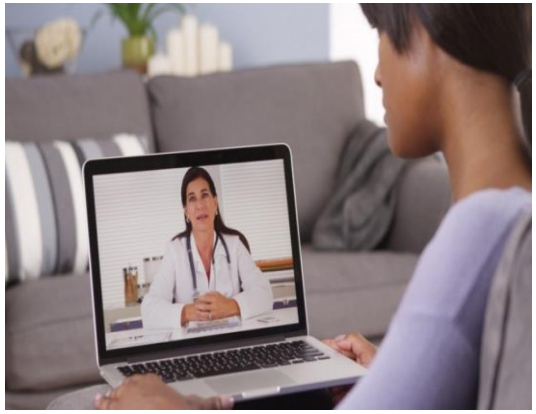
Remote Patient Rounding

EMR:

- Checking in on patient status
- Monitoring AEs and SAEs
- Watching for updates on Labs and Vitals
- Notes

Communication with Care Team :

- Connecting with Nursing Team
- Attending's and Residents
- Social Worker
- EPIC Haiku



Communication with Participant :

- More Frequent
- Establishing Rapport and Trust
- Connecting with Family

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Conducting In Person Study Visits with COVID-19 Precautions

- Protection for your staff and the participant
- Eliminating paper sources
- Use of devices that can be wiped down
  - Rotate every 4 days
- Plan ahead and provide detailed instructions
- Limit time during visit

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Innovation…… Expanding Access

greenphire®

GLOBAL HEALTHCARE SERVICES
Building relationships

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Case Study

- New Study: Industry funded Phase III Clinical Trial Involving New Drug Intervention in COVID-19 Positive Inpatients
  - Drug to be dispensed inpatient
  - Follow Surveys will need to be conducted inpatient/outpatient
  - Follow up blood collection will need to be collected inpatient/outpatient
  - How do we get this started?
    - Screening
    - Contract
    - Materials/PPE
    - Specimen Collection
    - Follow Up Visits

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