

## Clinical Researcher

April 2021

### HOME STUDY TEST

*Diversity, Equity, and Inclusion in Clinical Research*

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## **A Clinical Research Center's Story of Change and Adaptability During COVID-19**

Holly Bookless, BSN, RN, NE-BC; Paula Smailes, DNP, RN, CCRP; Todd Lusch, BA; Deanna Golden-Kreutz, PhD



What was originally known as the extramural General Clinical Research Center (GCRC) program was funded from the 1960s, first by the National Center for Research Resources within the National Institutes of Health (NIH), and then as part of the Clinical and Translational Science Awards (CTSA) program via NIH's National Center for Advancing Translational Sciences up until about seven years ago.<sup>{ 1 }</sup> While the NIH-backed funding dynamic has changed over the years and the GCRC itself has been defunded, NIH CTSA support to academic

medical centers (AMCs) has had a lasting impact. With or without current CTSA funding, integral programs at AMCs across the United States continue to yield successful research thanks to infrastructure created with federal help for facilitating studies that may be otherwise challenging for investigators to complete.

The Clinical Research Center facility (hereafter referred to as “the center” in most cases) at The Ohio State University Wexner Medical Center (OSUWMC) is now based within the College of Medicine's Center for Clinical Research Management and includes 11 beds, a metabolic kitchen, a processing lab for biological samples, and an analytical and development lab for assays.<sup>{ 2 }</sup> The center's staff consists of a nurse manager, a fiscal officer, two clinical research coordinators, six nurses, a registered dietitian, two clinical research assistants, and three research lab technologists. These resources currently support 130 active protocols and involve more than

2,500 participant visits per year. Studies span multiple therapeutic areas in Phases I through IV for both inpatient and outpatient settings. While the predominant hours are 7 a.m. to 5 p.m. Monday through Friday, 24/7 care can be provided when necessary for inpatient participant studies.

### **COVID-19 Impact on Business Operations**

While the normal, busy operations of the center were occurring a year ago, the threat of COVID-19 came to fruition when the Governor of Ohio announced on March 12, 2020 that the state would be shutting down many operations to help prevent the spread of COVID-19. With that, research leadership began determining which research studies would continue versus those that should temporarily stop. It was decided that only therapeutic trials would be continued. While most studies did well shutting down, concern did exist for some investigators with respect to study and funding timelines.

The Clinical Research Center at OSUWMC, with which all the authors of this article are engaged, remained open and continued research activity. Because of this, we were able to help with studies that did not otherwise have available research staff.

### **Alternative Work Arrangements**

With a reduction in workloads, initiatives were created to keep staff off campus when possible. Some center staff transitioned to work from home and needed assistance with resources, which included setting up equipment and network access. Guidance from research leaders was provided for what activities would be appropriate to do from home. When applicable, staff were assigned work that did not involve direct participant care, such as data entry, standard operating procedure development, equipment ordering/inventory, and professional development.

One particular concern related to the possibility of COVID-19 exposure for the center's staff and participants, along with the possibility of transmission. Therefore, staff were also assigned to develop safety workflows to mitigate COVID-19 risk when working at the center.

## **Supporting the Health System**

### *Space*

As with most AMCs, space is a hot commodity at OSUWMC. As a result, the medical center conducted an assessment of space to determine what areas could be used for a possible rise in COVID-19 admitted patients, including use of the Clinical Research Center. With a possible upsurge of COVID-19-positive patients, leadership determined that the center could possibly house COVID-19-positive patients or formerly positive patients awaiting a second negative swab.

The building that houses the center also includes the medical center's rehabilitation hospital. The rehabilitation hospital began to have space issues related to the need to keep patients in private rooms for proper distancing; for this reason, patients were moved into open beds located in the center. Research supplies and equipment had to be moved and stored in office spaces and other rooms to accommodate the rehabilitation patients moving in temporarily. Rehabilitation patients without COVID-19 were sent to the center and occupied nine beds. Since rehabilitation nursing is a specialty area, the associated nursing staff followed these patients to care for them on our unit.

The center housed the rehabilitation patients from the end of April until July 2020. In mid-July, the center returned to normal operations; however, in mid-August the rehabilitation patients returned due to space issues. This time, the move was simplified by sharing some supplies, while keeping important billable and research supplies separated. As a result, "research only" space for staff and research equipment was created. The ultimate configuration of the center during this time and currently is that COVID-19-positive participants are on one end of the unit (three beds), COVID-19-negative research participants on the opposite end (three beds), and medical/surgical patients from University Hospital in the middle (six beds, with three being semi-private). Specialty equipment for the center had to be moved out and is being stored until normal operations resume.

## *Staff*

While the center's operations were being revised, a plan for redeployment of staff to other areas of the medical center began in response to the potential increase in hospital occupancy due to inpatient and critically ill COVID-19 patients. Five of the six existing nursing staff were identified for potential deployment to assist with a potential COVID-19 surge. In preparation, these nurses underwent specialized training for the electronic medical record and general patient care; this included possible deployment to intensive care units, depending on nursing experience. To date, there has been no need to deploy center staff to other units. Hospital and research leadership determined that research staff would be one of the last groups to be deployed due to their critical role with forwarding the research mission, including the conduct of important therapeutic COVID-19 studies at our AMC.

## **Conducting COVID-19 Research**

When the majority of the world was closed due to the emerging pandemic, the Clinical Research Center needed to continue supporting the medical center's activity of direct patient care through research while also developing processes to manage the impact of the COVID-19 virus. Initially, the center began working on several studies related to exposures to COVID-19 and frontline healthcare workers. Overall, the center completed close to 1,300 visits with healthcare workers from May to July 2020. This experience prepared the team to move forward quickly when the College of Medicine's Office of Research approved a restart of both non-COVID-19 and COVID-19-positive studies in July 2020.

The first study was for those with mild to moderate COVID-19 symptoms for an outpatient monoclonal antibody study. This study required participants to be onsite at the center. At the same time, COVID-19 vaccination research was preparing to start. This research required the center to complete visits if the participant became ill after being vaccinated.

### *Challenges and Solutions*

These studies necessitated consideration regarding the logistics of COVID-19-positive and COVID-19 high-risk participant movement and samples. A COVID-19 Clinical Care Committee reviewed the research protocols allowing COVID-19-positive participant studies at the center. As part of the review process, an epidemiologist walked through the unit with the study team, principal investigator, and the center staff. Questions arose about processes that needed to be developed, including the following:

- What building entrance should be used for COVID-19-positive participants?
- Where should personal protective equipment (PPE) be sourced in order to not interfere with clinical needs for PPE?
- How do we complete procedures and handle samples safely with COVID-19-positive participants?
- How do we lessen our staff's exposure and decrease their overall time at the bedside with COVID-19-positive participants?
- How can we lessen the risk for COVID-19-negative inpatients and non-COVID-19 research participants on the unit while completing COVID-19-positive studies?
- How will the rooms be cleaned after COVID-19-positive participants leave?

To answer the questions about these challenges, solutions were created (see Table 1). To execute COVID-19-positive studies, the study sponsor or sponsoring department purchased PPE and other necessary supplies. N100 masks and replacement filters were supplied by our organization. Special training for proper donning and doffing of PPE was reviewed with staff as provided by the medical center. Hand hygiene was stressed, with hand sanitizer dispensers being located in all patient rooms and outside all patient doors. Institutional hand hygiene policy requires nurses to clean hands upon entry and again when leaving patient rooms, after touching any surfaces, and prior to and after gloving and/or any patient contact.

**Table 1: Challenges and Solutions During the Pandemic**

<b>Challenge</b>	<b>Solution(s)</b>
Shortage obtaining supplies/PPE	<ul style="list-style-type: none"><li>• Ask sponsor to provide first, then organization.</li></ul>
COVID-19 patient logistics	<ul style="list-style-type: none"><li>• Consult epidemiology for staff workflows and participant activity.</li><li>• Develop guidance for unit activity and participant safety.</li></ul>
Staff working from home	<ul style="list-style-type: none"><li>• Assign remote duties such as data entry, policy development, and computer-based learnings for professional development.</li><li>• Provide computers and monitors and ensure connectivity.</li></ul>
Study teams and center staff fears and concerns for COVID-19 transmission	<ul style="list-style-type: none"><li>• Provide emotional support.</li><li>• Provide education related to safe COVID-19 practices.</li><li>• Refer to employee assistance program for mental health services.</li></ul>
COVID-19-positive patient exposure time	<ul style="list-style-type: none"><li>• Communicate through the Updox system and conduct virtual participant monitoring.</li><li>• Conduct continuous assessment of processes and support to adjust procedures quickly as needed.</li></ul>
Research participant safety and prevention of COVID-19 transmission	<ul style="list-style-type: none"><li>• Cluster COVID-19-positive participants away from non-COVID-19-positive participants.</li><li>• Terminally clean rooms after use.</li><li>• Use PPE and established hand hygiene practices.</li></ul>

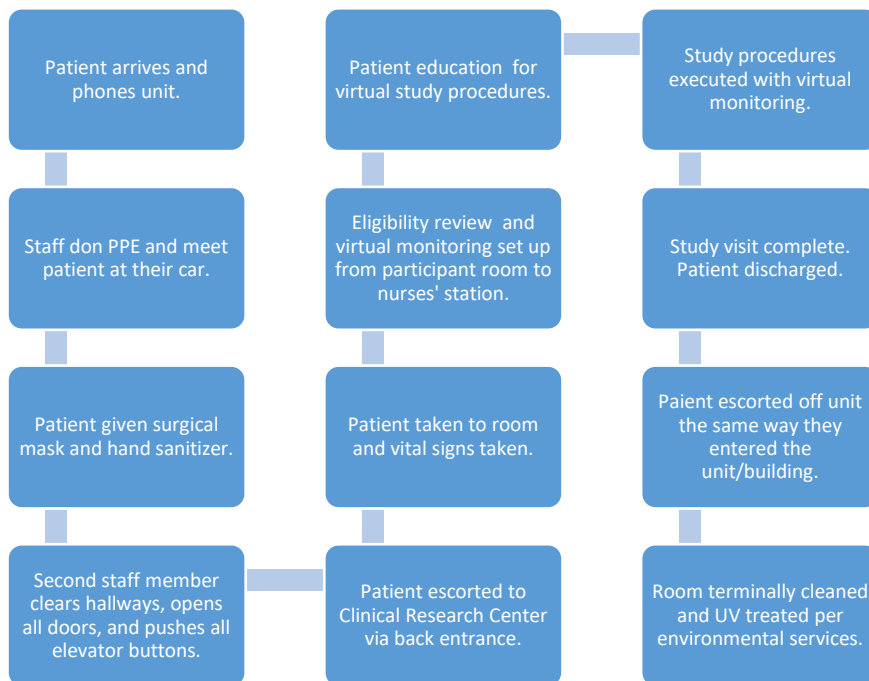
Collaboration to reopen research activities was done with the following support areas:

- The Clinical Research Center Registered Dietitian worked with the Respiratory Therapy and Epidemiology Departments to understand metabolic cart equipment operation and cleaning after use for COVID-19-positive participants, which is designed to perform indirect calorimetry, oxygen consumption, and exhaled CO<sub>2</sub> tests.
- Epidemiology was consulted for ongoing review of procedures to ensure processes were safe.
- Respiratory therapists were involved in spirometry and exercise studies so that their input could be gained into the safe operation and cleaning of equipment during the pandemic.

### *COVID-19-Positive Study Participants in the Center*

COVID-19-positive study participants were screened prior to arrival at the center to ensure eligibility. If during the recruitment process it was determined that a participant did not qualify, they did not come to the unit and were advised to follow up with their primary care physician. However, upon arrival eligibility was again reviewed; participants could potentially be screen failures once at the unit due to unstable vital signs. For COVID-19-positive participants coming to the center, a workflow was developed to ensure safety for staff and patients (see Figure 1).

**Figure 1: COVID-19-Positive Participant Workflow in the Clinical Research Center**





### *COVID-19-Positive Participant Arrival*

After the COVID-19-positive participant parks their car, the participant calls the center nurses' station to notify staff of their arrival and the assigned number of their specific parking spot. The participant would remain in their car while CRC nurses donned the proper PPE including N100 mask, hair cover, face shield, gown, and gloves. The nurses would meet the participant at their car with hand sanitizer, a surgical face mask for the participant to wear, and an ID band to identify the participant.

The participant was not permitted to touch anything, including the door, elevator button, etc. In some cases, they would be taken by wheelchair to the unit. Participants and staff would enter the back side of the unit away from the nurses' station and most other unit activity. Another staff member would help with opening doors, using their badge for entry, and clearing the hallway of patients and staff.

There was a commitment to having strong communication with other staff working in the building, so they were aware of what was occurring. Height and weight were collected on the way to the room on a designated scale. These participants had mild to moderate symptoms and only a few participants had any shortness of breath or cough.

### *Study Execution*

Once the research participant was in a center room, vital signs, pulse oximetry, and a general medical/surgical history were collected. Virtual monitoring was done with the utilization of Updox to reduce staff exposure time with the COVID-19-positive participant. (Updox is a Health Insurance Portability and Accountability Act-compliant, web-based communications platform using video to interact with patients virtually.)

A study doctor would perform the physical and ensure participant eligibility before nurses started their research care. Once the participant qualified, the center nurse worked with the participant to do urine pregnancy testing (if applicable), IV placement for blood work, vital signs, and review of surgical, medical history, current medications, and allergies. The nurse also completed a nasal

swab and saliva sampling for the COVID-19-positive diagnosis and, most importantly, ensured the participant is comfortable.

For ongoing monitoring, a laptop was placed in participant's room and a second laptop was placed at a desk near the telemetry monitoring system. The link to Updox is sent to the nurse caring for participant. The center staff member opens the link on the laptop in the room and ensures video and sound are enabled. Another staff member or nurse stationed near the telemetry machine ensured the participant was visible, including the ability to see chest rises for respiration monitoring, face, and IV medication pump reading.

Staff donned and doffed PPE several times depending on study activities per medical center policy. Virtual monitoring helped to reduce the amount of PPE used and lessened staff exposure, thus promoting safety.

For studies with investigational IV medication administration, the nurse caring for the participant does as many activities as possible pre-infusion/medication administration. The nurse also ensures a good visual is in place from the desk via the laptop in the participant's room. The participant is instructed on how and when to take their temperature when blood pressure monitoring is completed. Pulse oximetry measurement is checked continuously and this can be seen virtually at the nurse station.

A staff member located at the center's nurse station checks respirations, heart rate, and blood pressure every 15 minutes and continuously monitors the participant during infusions to ensure there are no issues with tolerance and side effects. The nurse caring for the participant must re-enter the room when investigational medication is ready per pharmacy and leaves the room so virtual monitoring can be done at the desk.

### *COVID-19 Study Samples*

Samples are sent to the analytical and development lab for processing within the Biosafety Cabinet. For nasal swabs, once the specimen is in the medium, it is believed to no longer pose a threat of exposure to staff; however, it is still handled per lab safety standards and required PPE. The swab is placed in a biohazard bag and is wiped with a disinfecting wipe. A second biohazard

bag is placed over the first biohazard bag and is also wiped. Glove changes and hand washing occur before and after each bag is applied. Swabs are delivered to the lab and they are labelled as COVID-19-positive, packaged, frozen, and shipped.

### *Patient Discharge*

Per consult with epidemiology, Sani-wipes® are used by the nurses upon discharge to effectively kill COVID-19 on surfaces and provided by the institution for this purpose. After COVID-19-positive patients are discharged, the room is terminally cleaned and UV-treated per environmental services and institutional policy.

### **Support for Non-COVID-19 Studies**

COVID-19 research was being conducted at the same time as non-COVID-19 studies. Staff members were given a rotation of work assignments (concentrating on non-COVID-19-positive assignments on some days and focus on COVID-19-positive assignments on others) and highlighting and celebrating when goals such as a top recruiting site and/or the first site to enroll a participant were achieved.

Discussions occurred with individual research teams and lead center staff regarding the safety and plans to minimize exposure to COVID-19 for participants and research staff. The center's nurse manager oversaw these discussions while the staff nurses would review the revised center processes and provide insight on institutional rules and policies.

Study teams were asked to do COVID-19 pre-screening on all participants. Participants were met outside due to the locked doors of the center building. Participants were required to wear surgical masks provided by the study team. Masks were essential and had to be worn by the participant for the entire research visit despite the length of the study visit. Some visits could last for 10 to 12 hours, and education was provided to the participant prior to study visits regarding the need to wear a mask the entire visit.

## The New Normal

As we continue to work toward routine research operations, the COVID-19 pandemic promises to bring more barriers to the conduct of clinical research. However, overcoming challenges and capitalizing on the solutions we've developed will hopefully allow the Clinical Research Center to be better prepared in the future. At the same time, potential new options for the growth of research operations exist with tele-research visits, electronic and virtual consenting, and other virtual research activities.

Many future opportunities to study and learn about COVID-19 are inevitable. The processes and procedures the center has in place, including support from research leaders, essential open communication, participant safety, and teamwork among staff, will sustain the operations of our center for both COVID-19-positive and COVID-19-negative studies. This promises to promote the research enterprise at our organization and beyond.

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**Holly Bookless, BSN, RN, NE-BC**, ([holly.bookless@osumc.edu](mailto:holly.bookless@osumc.edu)) is the Nurse Manager for the Clinical Research Center/College of Medicine's Center for Clinical Research Management at The Ohio State University Wexner Medical Center.

**Paula Smailes, DNP, RN, CCRP**, ([paula.smailes@osumc.edu](mailto:paula.smailes@osumc.edu)) is a Visiting Professor at Chamberlain College of Nursing and Senior Systems Consultant at The Ohio State University Wexner Medical Center.

**Todd Lusch, BA**, ([todd.lusch@osumc.edu](mailto:todd.lusch@osumc.edu)) is Director of Clinical Research Operations and Implementation for the College of Medicine's Center for Clinical Research Management at The Ohio State University Wexner Medical Center.

**Deanna Golden-Kreutz, PhD**, ([deanna.golden-kreutz@osumc.edu](mailto:deanna.golden-kreutz@osumc.edu)) is the Senior Director for the College of Medicine's Center for Clinical Research Management and Associate Clinical Professor for the Department of Internal Medicine at The Ohio State University Wexner Medical Center.

## **Diversity in Clinical Trials: Going Beyond *Why* to *How***

Scott Gray



It's no secret that patient diversity is a major issue in clinical trials, and that a lack of diversity makes it difficult to measure efficacy and safety. However, even given the U.S. Food and Drug Administration's [recent guidance](#), there is not a lot of actionable advice for trial sponsors and research organizations looking to increase enrollment among historically underrepresented groups. The conversation has stalled at *why*, and the time is long overdue to start talking about *how*.

### **The Benefits of Diversity in Clinical Trials**

One goal of all clinical trials should be to represent the affected population as a whole. Because most conditions are not specific to a single demographic, sample populations shouldn't be either. Ethically, a lack of representation in trials raises concerns about ensuring equal access to new treatments and cures. A person's socioeconomic status or demographics should not exclude them from participating in a clinical trial or from being assured the approved treatment will be safe and effective for them once approved.

Historically, 60% to 70% of clinical trial participants have been white males because they were the ones who could afford the cost of travel and the time off work to participate. Today, ethnic diversity in clinical trials continues to be an issue. For instance, in the United States, African Americans make up 13.4% of the population, but only [5% of clinical trial participants](#). The disparity is even worse for the Hispanic or Latino population; they make up 18.1% of the U.S. population and only 1% of trial participants. Asian Americans account for 6% of the population

and only 1% in clinical trials, and two-thirds of clinical trials are absent any Native American participation.

Such lack of diversity is not limited to U.S. trials, however. One recent study of trials across 29 countries over the past 21 years shows that [86% of participants were white](#). The disparity is concerning because it is scientifically crucial to understand how a new drug or therapy affects patients of varying ages, genders, and ethnic backgrounds, as reactions to many new treatments are proven to differ depending on the individual's demographics. For example, African Americans react differently than white populations to certain blood thinners and [asthma medications](#).

Proportional representation in clinical trials helps to accurately understand how or if a drug affects a particular demographic group negatively or differently. More investigation can then define the issue or address it before the therapy receives approval. Representation is essential because once a drug is commercially available, access will not be restricted to certain demographics, so a clear understanding of each demographic's reaction is an imperative *before* going to market.

### **Practical Methods for Overcoming Barriers to Participation**

To achieve our shared diversity goals, we need to directly address the challenges historically underrepresented populations experience in clinical trial participation. Many of these barriers could be mitigated through improved communication with targeted populations. Educating each group on the importance of trial participation and the potential benefits for participants can go a long way to increase enrollment. For instance, ensuring these groups are aware of the compensation and travel stipends available can sway patients to become participants. In the U.S., this might include discussing the Ensuring Access Act, which deducts the first \$2,000 a patient receives for clinical trial participation from federal benefit eligibility determinations and aims to remove some of the financial barriers lower-income families experience.

This type of education requires dedicated resources for community outreach, including building relationships with community leaders in underrepresented demographics to act as knowledge ambassadors. It should also include direct communication with patient advocacy groups, patients

and caregivers, and physicians to help inform the design of clinical trial protocols to mitigate any steps that discourage participation.

Additionally, trials can be designed with more resources and communications to make trial participation less burdensome for participants. For example, choosing [payment or reimbursement methods](#) that best serve a particular population and partnering with companies that manage patient logistics and expense prepayment can significantly reduce the barriers to participation and improve retention rates in trials.

By providing direct support to patients from enrollment through the end of the clinical trial, these services ease the financial, logistical, and psychological barriers to participation. Where possible, increasing site locations in communities with high populations of underrepresented populations and holding recruitment events during weekend and evening hours can also make trials more accessible.

Addressing these challenges may not only increase participation, but also [increase the participants' satisfaction](#) with the entire experience.

### **How Dedicated Patient Coordinators Impact Trust and Retention**

Recruiting diverse populations to participate in trials is only the first challenge. Participants must be supported and remain in the trials through completion in order to be represented in the trial outcomes. Partnering with a company that provides patient logistics coordination and patient support may be one of the best tactics available to improve retention rates while reducing the burden on trial staff. By providing coordinators who are assigned to each participant through the length of the trial, patients receive personalized support for travel, financial prepayments or reimbursements, pandemic-related issues, relocation services, and other logistical support they may need.

These services are most effective when coordinators provide one-on-one support and are matched with participants based on things like location or time zone, culture, and language. This approach reduces the burden on participants and caregivers, allowing them to focus on their

health and improves trust and satisfaction with the experience, increasing the likelihood that a participant will remain in the trial through completion.

### **Unique Challenges in Global Studies and Studies of Rare Diseases**

Achieving diversity in clinical studies involving rare and ultra-rare diseases presents its own challenges. There are significantly smaller patient populations available in rare disease studies, so special efforts are necessary to recruit and retain them. In the rare disease space, a specific clinical trial may be the patient's only hope for medical treatment, so including them isn't just ethically necessary; it's also medically necessary.

In these cases, extensive travel is generally unavoidable as patients may be spread out across the world, or in the case of a genetic condition, multiple patients may be concentrated in one specific geographical area in a different country from the clinical site. For example, a significant amount of research may be done at a single site in Frankfurt, Germany, but the babies who would benefit from this life-saving research are clustered in China and India. In these cases, entire families may need to relocate to Germany for months, requiring airline travel where medical equipment is permitted on-board the plane, apartment rentals, translation services so the family can communicate with medical staff, and more.

Additionally, patients may be very ill or have diseases that are debilitating and impact cognition or mobility. A patient's location or ability level should have no bearing on his or her right to participate in a clinical trial, but these factors do present challenges.

This is another area where patient logistics companies can provide invaluable support to improve trial performance. Their trained coordinators understand the medical challenges faced by patients and caregivers and can provide complex cross-border support, translation and interpretation services, and logistics management for participants in remote locations or with complex medical needs. Their needs might include visa and passport procurement, managing exchange rates and reimbursement, navigating local regulations, and coordinating multi-leg travel and relocation efforts.



When you consider the complicated nature of participating in rare and ultra-rare disease trials, it is no wonder that drop-out rates are typically relatively high for these types of studies. It has been shown that [85% of all clinical trials](#) are delayed due to not retaining enough participants to continue, and that the cost of just one patient dropping out of a rare disease trial far exceeds the average cost of losing a participant in a common clinical trial of [approximately \\$20,000](#). Considering how expensive and time-consuming it is to lose a patient, investing in services that increase retention rates and retain diverse participant pools once they are recruited is a logical choice.

### **Diversity is Our Responsibility**

We can all agree that achieving diversity in clinical trials is complicated. However, with these specific steps to improve community outreach, education, and accessibility—along with an investment in retaining those populations once they are recruited—adequate representation is achievable.



**Scott Gray** is co-founder and CEO of [Clincierge](#), a firm focused on patient logistics management for clinical trials.

## **ACRP HOME STUDY**

### **CLINICAL RESEARCHER—APRIL 2021 (VOLUME 35, ISSUE 3)**

#### *Diversity, Equity, and Inclusion in Clinical Research*

#### **Article #1: A Clinical Research Center's Story of Change and Adaptability During COVID-19**

##### LEARNING OBJECTIVE

After reading this article, the participant should be able to summarize the safety issues of concern and the steps taken to address them at an academic medical center conducting human subjects research during the COVID-19 pandemic.

##### DISCLOSURES

Holly Bookless, BSN, RN, NE-BC; Paula Smailes, DNP, RN, CCRP; Todd Lusch, BA; Deanna Golden-Kreutz, PhD: *Nothing to disclose*

**1. The General Clinical Research Center program was established under which of the following entities?**

- a. U.S. Food and Drug Administration
- b. Centers for Disease Control and Prevention
- c. National Institutes of Health
- d. Department of Health and Human Services

**2. Measures undertaken to ensure safety for staff at the Clinical Research Center described in this article included which of the following?**

- a. Enabling work from home and workload reallocation.
- b. A yearlong switch to entirely non-COVID-19 studies.
- c. Prohibiting study participants from visiting the center.
- d. A pivot to conducting only Phase I studies in healthy subjects.

**3. In cases of shortages, which of the following should be approached first in order to have personal protective equipment supplied for a clinical trial?**

- a. The institutional review board.
- b. The study sponsor.
- c. The principal investigator.
- d. The U.S. Food and Drug Administration.

**4. Which of the following departments is noted as being beneficial to consult with regarding patient logistics when conducting COVID-19 research?**

- a. Epidemiology
- b. Finance
- c. Transportation
- d. Regulatory

- 5. Based on the center's experience, which of the following should be prepared when considering COVID-19-positive patient logistics at a study site?**
- Legal indemnification policies for physicians and staff in case patients become infected.
  - Standard operating procedures for conducting studies without personal protective equipment.
  - Guidance for unit activity and participant safety measures affected by the pandemic.
  - A series of steps for rapid shutdown of the site if sponsors refuse to reimburse new procedures.
- 6. Staff at the center did which of the following when COVID-19 participants arrived at the site?**
- Called for the site's infection control specialist to be on hand for the visit.
  - Allowed participants to enter building only if they were masked and could do so under their own power.
  - Donned personal protective equipment and met the participant at his or her car.
  - Prepared all dosages of study drugs to be given to participant in the parking lot.
- 7. Techniques undertaken by the center to reduce the potential for COVID-19 exposure for research participants included which of the following?**
- Conducting participant visits in temporary research centers in the parking lot.
  - Communicating solely with participants' non-infected family members.
  - Requesting that participants make a complete change of clothing as each visit ended.
  - Monitoring of participants through virtual technology.
- 8. Which of the following was done inside the center for the sake of preventing COVID-19 transmission to staff?**
- Limiting all clinical research coordinators to seeing just one participant per day.
  - Terminal cleaning of visitation rooms between all COVID-19-positive participants.
  - Supplying multivitamin boosters to staff during each COVID-19-positive participant visit.
  - Having COVID-19-positive participants decontaminated before leaving the site.
- 9. Cleaning steps taken after COVID-19-positive study participant activity at the center were noted as including which of the following?**
- Treatment with UV light.
  - High-pressure water cleansing.
  - Anti-bacterial aerosol spraying.
  - Marking roped-off area as "hazardous."
- 10. Participants in non-COVID-19 studies at the center were required to do which of the following?**
- Ensure that no one else had just been in their visit room.
  - Wash all doorknobs and handles they touched when visiting.
  - Reuse gowns from their previous visits to the center.
  - Wear surgical masks for the entire research visit.

*[TEST CONTINUES ON FOLLOWING PAGE...]*

## Article #2: **Diversity in Clinical Trials: Going Beyond *Why* to *How***

### LEARNING OBJECTIVE

After reading this article, the participant should be able to explain multiple challenges and ethical concerns related to lack of diversity in clinical trials and describe steps for addressing them.

### DISCLOSURE

Scott Gray: *Nothing to disclose*

#### **11. What is noted by the author as an ethical concern tied to lack of representation in clinical trials?**

- A. It will force sponsors to shut down promising drug development pipelines to appease regulators.
- B. It prevents profits from marketed treatments being distributed equitably across national boundaries.
- C. It risks some people's assurance that an approved treatment will be safe and effective for them.
- D. It presents the appearance that researchers are favoring certain populations for participation.

#### **12. According to the author, which of the following is an accurate statement regarding ethnic diversity in clinical trials?**

- A. Historically, only about half of trial participants have been white males.
- B. Hispanics/Latinos participate in trials at lower rates than African Americans.
- C. Participation by Asian Americans is rising at unprecedented levels this decade.
- D. Native Americans have never been invited to participate in clinical trials.

#### **13. What is noted as a trend in diversity in trials from a study of 29 countries outside the United States?**

- A. Less than half the countries include women in trials.
- B. More than two-thirds of cancer studies include no African Americans.
- C. Less than one in 10 pediatric trials happen outside the U.S.
- D. More than three-quarters of participants were white.

#### **14. Why should diverse patient populations be included in trials before a product is marketed?**

- A. Out of safety concerns because access to approved drugs is not limited to certain demographics.
- B. Out of financial concerns because trials high in diversity cost significantly less to complete.
- C. Out of regulatory concerns as the FDA will not approve drugs whose non-U.S. trials lacked diversity.
- D. Out of fears of bad publicity when physicians refuse to use drugs approved in non-diverse conditions.

#### **15. Which of the following pieces of legislation deducts some of the money patients receive for being in a trial from their federal benefit eligibility determinations?**

- A. The Improving Access to Clinical Trials Act.
- B. The Ensuring Access Act.
- C. The Right to Try Act.
- D. The Federal Food, Drug, and Cosmetic Act.

#### **16. The author recommends study sites partner with which of the following to reduce barriers to participation and improve retention rates in trials?**

- A. Companies that manage patient logistics and expense prepayment.
- B. Companies that provide trial supplies and insurance at the lowest prices.
- C. Companies that have offices in every region of the U.S. and internationally.
- D. Companies that recruit from universities with many international students.

**17. The author recommends providing which of the following so that patients in trials will receive personalized logistical support?**

- A. Wearable devices that will track patients' locations and vital signs at all times.
- B. Vouchers for expenses that can be used at most major automobile rental services.
- C. Coordinators who are assigned to each participant through the length of the trial.
- D. Warnings that patients should not make contact with each other in between study visits.

**18. What kind of studies generally involve extensive travel because patients in them are so widespread?**

- A. Central nervous system studies.
- B. Medical device studies.
- C. Lung cancer studies.
- D. Rare disease studies.

**19. Which of the following is noted as an example of the kind of support a patient logistics company might provide a rare disease patient traveling to another country to participate in a trial?**

- A. Flights on board the company's private jets.
- B. Translation and interpretation services.
- C. Waiver of U.S. Customs screening procedures at airports.
- D. Preferred access to NIH-sponsored studies.

**20. How does the average cost of a patient dropping out of a rare disease trial compare to the cost of one dropping out of a standard trial?**

- A. The cost is far less.
- B. The cost is about the same.
- C. The cost is far greater.
- D. The relative costs cannot be determined.