Setting Up a Clinical Research Home Office During a Pandemic

By Norman M. Goldfarb

The COVID-19 pandemic has caused many organizations to send personnel home to work in a “home office.” In addition to the challenges of setting up an office in a home that might lack the necessary space, floorplan or absence from distractions, there are the additional challenges of maintaining the security, patient safety, and regulatory compliance required by clinical research.

This article discusses steps you can take to properly set up and operate out of your home office in the middle of a pandemic. Given the current circumstances, these steps should be part of a larger business continuity plan for your organization.

Work Considerations

- **Regulatory compliance.** The regulations that apply in your office also apply at home, including FDA’s recent guidance on dealing with COVID-19. Ask someone in regulatory compliance or at your IRB how regulations like HIPAA and Part 11, which are routine in the office, need extra care or different processes in a home office.

- **SOPs.** Make sure your standard operating procedures (SOPs) accommodate working from a home office. For example, will you have access to paper documents that need to be wet-signed within three days?

- **Communicating with colleagues.** Gather telephone numbers and email addresses for your colleagues. Know whom to contact in which circumstances. Your organization might facilitate communications by setting up a webpage, hotline or Slack group.

- **Email communications.** Keep up with study-specific communications to document and explain what is happening in the study.

- **Protocol violations/deviations.** Violations and deviations will occur. For example, study visits and other activities will be missed. Plan ahead and keep detailed, contemporaneous notes.

- **Certified copies.** If you need to convert paper documents (or other media) into certified digital copies, make sure you have an SOP and the technology in place. It is safer to scan documents in their current location than moving them between locations.

Your Home Office

- **Furniture.** You are going to be spending a lot of time in your home office, so invest in a comfortable chair; efficient, ergonomic furniture; and good lighting. Your employer might subsidize the investment.

- **Electrical Power.** Install a good power strip with a surge protector and maybe an uninterruptible power supply (UPS) or backup power. Do not overload your electrical circuits. Avoid a dangerous tangle of electrical cords.

- **Office hours.** Establish boundaries for yourself, your colleagues, your patients, your family, and others. Make sure your work time is spent working and your
non-work time is spent not working (more than usual), except under specified circumstances.

- **Physical security.** Make sure your home and home office are secure. Lock up documents not in use. You might want to obtain a fire-safe box for the most important documents. Shred obsolete documents that contain private or confidential information. Make sure passersby cannot view documents or your computer screen either from within your home or through a window. Even if you completely trust everyone, accidents can happen.

- **Telephone.** If you are using the same telephone during both work and non-work hours, figure out how you are going to answer incoming calls and what your voice message should say. Consider setting up a separate line.

- **Ambient sound.** Minimize crossover sounds between your work and personal/family spaces. You might need to soundproof a door.

### Your Home Computer

- **Your work computer.** If possible, avoid crossover problems by using separate computers for work and non-work activities. Make sure your work computer is big and fast enough for your needs. If you prefer using a laptop, get one that can accommodate an external monitor and maybe an external keyboard.

- **Computer security.** Make sure your data backup (preferably in the cloud) and your antivirus and other protective systems are functioning properly.

- **Access.** You might want to set up two-factor authentication where possible. If using a home WIFI network, guard access with a strong password. It can be hard to remember multiple passwords so use a password manager, but only one that your management has approved.

- **Remote access.** Make sure you can securely access your organization’s computer applications over a high-speed Internet connection. Ask your IT department about setting up a virtual private network (VPN) that will open your organization’s private network to you and automatically encrypt/decrypt any data transmissions.

### Conclusion

When setting up a home office in the middle of a pandemic, things can go wrong, so take the time to do it right. Get advice from online articles and colleagues who are already working at home.

When working at home, you will need to make an extra effort to stay connected with your colleagues and informed about events within your studies, your organization, and the world at large. Take advantage of online resources, such as websites, publications and webinars.

We are now dealing with a serious crisis that affects almost everybody in the world, often in unexpected ways. If anything, we are now more susceptible to a second or even a third crisis. Assume the unexpected can happen.

Many people who are now setting up a home office will never move back to their former office office, so make yourself comfortable.

See you on the other side!
Reference


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