“Clinical Research: From Proposal to Implementation”

Robert D. Toto and Michael J. McPhaul, editors, 2011, 255 pages, Lippincott Williams & Wilkins, $34.00

Review by Norman M. Goldfarb

“This book has been selected for The First Clinical Research Bookshelf Essential reading for clinical research professionals

Identify Clinic Space Needs

Clinic space location is important should ideally be made as convenient as possible for potential study subjects. This is not always possible to control by the investigator but should be a priority for location for junior investigators. It is always preferable to conduct screening on site of the investigators’ laboratory or office, but screening at off-site locations may be needed in some circumstances in order to achieve recruitment goals. Investigators should estimate the amount of space needed to conduct the screening and evaluation process, and then set about identifying the space and equipping it accordingly. The space must be secure to protect confidential information whether written or stored in encrypted computer data files.

A minimum amount of space should include an interview and examination room for the study subject and office space for the individual(s) who will conduct the screening and evaluation process. Two hundred square feet of properly equipped space can be effective and efficient for conducting several studies simultaneously, depending on the size of the study populations and protocol specifics. The space should include desktop and file cabinet, telephone, fax, copy machine, and at least one computer with an Internet connection. A typical outpatient examination room with an examination table, height and weight station, desk-top, storage for patient examination and study supplies, measuring devices (e.g., sphygmomanometer, scale, etc.), sink for hand washing, and blood sampling supplies should also be within the clinic space. A refrigerator with a -20°C freezer and tabletop centrifuge for preparing body fluid samples is recommended for collection of blood and body fluid at screening or evaluation visits. The office space should include supplies for documentation and for creating labels and preparing samples for shipping and receiving as needed. It is highly desirable to have a private bathroom within the research space, but a separate private bathroom facility nearby the research clinic enclosure is workable.

The office space should be large enough for the investigator to conduct brief meetings with research team members (e.g., research nurse, collaborators). The examination room and office space should be separated from one another when possible so that privacy is ensured. In case screening and evaluation procedures must take place in the hospital setting, the patient’s hospital room and doctor’s station may suffice. In this setting, the investigator must be able to carry informed consent forms and data collection forms (or a laptop computer for data collection).
Investigators should design and arrange screening and evaluation clinic space in a manner that allows for security of study documents.

The chapter on data sharing and handling of genetic data includes a much more sophisticated discussion than might be expected in a book of this type, for example:

**Trails and Location-Based Patterns**

Many patients (and research participants) are transient and visit multiple institutions providing care. As such, a patient’s location-visit pattern is often distinguished and facilitates what has been termed a “trails” attack. In this scenario, a patient visits multiple hospitals, where his clinical and DNA-related data are collected. The facilities forward deidentified DNA records, tagged with the submitting institution, to a public centralized databank. Additionally, the hospitals send identifiable discharge records, including patient demographics and diagnoses, to a discharge database. Even if there is no clear biomedical relationship between the diagnosis codes and sequence markers in the DNA, we can track the hospitals a patient has visited (i.e., the “trail”) in the discharge data and the DNA records in the repository. Notably, this attack is generalizable in that trails can manifest in a number of environments.

The book includes 14 chapters:

- How to Launch a Successful Career in Clinical Research: Tips on Making the Most of Available Resources
- Institutional Review Board Approval
- Writing Informed Consent Documents and Obtaining Informed Consent
- Ethics of Data Sharing and Handling of Genetic Information
- Writing a Statistical Analysis Plan
- Protocol Implementation Procedures
- Screening and Evaluation
- Recruitment and Retention
- How to Set Up Your Database
- Budgeting Process and Management
- Understanding Food and Drug Administration (FDA) Regulatory Requirements for Investigational New Drug Applications (INDs) for Sponsor-Investigators
- Collecting Data
- Data and Safety Monitoring
- Presenting, Writing and Publishing Challenges

The 10 appendices mostly consist of templates for a consent form, HIPAA authorization, and such.

The book is available in bookstores.

**Reviewer**

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