This library of resources was compiled to centralize resources related to conducting and managing clinical trials. The resources are particularly helpful for physician investigators and research staff. A Task Force of the Research Community Forum, representing a range of community research stakeholder groups with a wealth of experience, compiled this list to help make it easier for research sites to find needed resources. Decisions to include resources were solely based on the Task Force’s own go-to resources, consultation with colleagues, and an environmental scan of available resources on these topics. Resources from commercial, for-profit entities are generally excluded from the library. The items listed are not necessarily endorsed by ASCO; they are listed based on the discretion and expertise of the Task Force.

This list is not exhaustive and will be updated periodically. Your feedback is welcomed! If you have ideas for content to add or edit, please email your suggestions to the ASCO Research Community Forum.

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Disclaimer: This library contains resources and templates that are provided as examples only for research programs to consider as they formulate their own resources. ASCO makes no warranties, expressed or implied, as to results obtained by individuals using the information and is not responsible for any action taken in reliance on the information contained herein.

When citing this Toolkit, or any of its components, please include the following content in the citation: American Society of Clinical Oncology Research Community Forum. Library of Resources: Conducting and Managing Cancer Clinical Trials. Alexandria, VA; American Society of Clinical Oncology; Aug 2020.

For more information contact researchcommunityforum@asco.org.
VI. Data Management

The resources listed below provide information on how to collect and manage research data. Resources on data protection are also provided. This list is not exhaustive and will be updated periodically.

This section includes the following topics:
A. Disaster Recovery Plan
B. Data Protection
C. Data Management and Storage
D. Managing Equipment and Facilities

A. Disaster Recovery Plan
(i.e., disaster recovery and business continuity plan)

- **Business continuity plan.** This FEMA resource diagrams a business continuity plan and offers resources to help sites plan for disaster.
- **Disaster preparedness and recovery plan.** This resource from the U.S. Small Business Administration provides an overview of disaster preparedness.
- **Guide to getting started with disaster recovery.** This guide from the Disaster Recovery Guide provides information, guidance, tips, and resources to support sites in establishing business continuity plans.
- **Disaster Recovery Information Exchange.** This non-profit association of professionals is dedicated to the exchange of information on all aspects of business continuity management, from emergency response to the resumption of business as normal.

B. Data Protection
(e.g., protocols, passwords)

- U.S. Department of Health and Human Services Office for Human Research Protections [Data Management Practices](#).
- U.S. Food and Drug Administration [Proposed Regulations and Draft Guidances](#) on clinical trials and trial participant protections
- Review [Selected U.S. Food and Drug Administration Good Clinical Practice and Clinical Trial Guidance Documents](#) for information on the agency’s perspective on good clinical practice and the conduct of clinical trials.

C. Data Management and Storage
(e.g., short-term and long-term data management, storage, and archiving)

- Corn M. [Archiving the Phenome: Clinical Records Deserve Long-term Preservation](#). *J Am Med Inform Assoc.* 2009 Jan/Feb;16(1):1-6. This article discusses the importance of long-term record storage and address common questions.
- National Cancer Institute [Best Practice for Biospecimen Resources](#). These voluntary guidelines provide an outline of how to incorporate Best Practices into a site’s internal procedures. The
guidelines are divided into two broad areas including "Technical and Operational Best Practices" and "Ethical, Legal, and Policy Best Practices"

- National Cancer Institute Office of Biorepositories and Biospecimen Research Technical and Operations Best Practice: Biospecimen Collection, Processing, Storage, Retrieval, and Dissemination

D. Managing Equipment and Facilities
(i.e., handling and managing equipment, instruments, and laboratory facilities)

- National Center for Biotechnology Information Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards. This online book discusses environment, health, and safety management systems, administrative and organizational concerns around the laboratory environment, practical concerns and relevant federal regulations around research laboratory practices.

- NIH Department of Acquired Immunodeficiency Syndrome (AIDS) Requirements for Pharmacy Facilities at Division of AIDS Supported Clinical Research Sites. This site provides policies and standard procedures related to requirements for DAIDS-supported pharmacies and the use of study products associated with DAIDS-supported and/or -sponsored clinical trials.

- World Health Organization Good Practices for Pharmaceutical Quality Control Laboratories. This resource advises on the quality management system within which the analysis of active pharmaceutical ingredients (APIs), excipients and pharmaceutical products should be performed to demonstrate that reliable results are obtained.