Conducting and Managing Cancer Clinical Trials
A Library of Resources

Chapter V. Management of Trial Participants
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:

For more information contact researchcommunityforum@asco.org.
V. Management of Trial Participants

These resources address the varied aspects of patient involvement in the clinical trial process. The resources cover topics including eligibility and accrual, consent process, adverse event/serious adverse event reporting, and specimen protocols. This list is not exhaustive and will be updated periodically.

This section includes the following topics:

A. Engaging Patients in your Research Program
   i. Representation of Underserved Populations
   ii. Geographic Barriers
   iii. Barriers to Enrolling Patients onto Clinical Trials
   iv. Broadening Eligibility Criteria
   v. Special Patient Populations
   vi. Financial Barriers for Patients

B. Patient Recruitment and Eligibility

C. Informed Consent Development, Implementation, and Documentation

D. Patient Management While on Study and Long-term Follow-up

E. Specimen Collection, Handling, Processing, Transporting and Destruction

F. Protocol Deviation Reporting and Prevention

G. Emergency Use of an Investigational Drug or Biologic Agent

A. Engaging Patients in your Research Program

The following tools, research, and other resources will help you create or improve your existing strategies for engaging patients in clinical trials.

- Advocacy Program Research Awareness Event Tool Kit for Community Cancer Centers. (Direct file download) This Research Advocacy Network toolkit offers information on how to plan a successful symposium to identify and support research advocates.
- Five Steps to Enhance Patient Participation in Cancer Clinical Trials Guide and Workbook. (Direct file download) This resource from the Education Network to Advance Cancer Clinical Trials offers resources including checklists, common questions, and sample plans to facilitate patient participation in clinical trials.
- Perlmutter J, Bell SK, and Darien G. Cancer research advocacy: past, present, and future. Cancer Res. 2013;73(15):4611-5. This article discusses the role of cancer advocates in research and presents a framework for successful research advocacy.
- Research Advocacy Network Advocacy program research awareness event tool kit for community cancer centers
- Education Network to Advance Cancer Clinical Trials (ENACCT), Community-Campus Partnerships for Health (CCPH). Communities as partners in cancer clinical trials: Changing research, practice and policy. 2008.
- Health Literacy in Clinical Trials. The Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard. www.mrctcenter.org/health-literacy.
- Refer to Chapter X. Research Organizations and Initiatives for information on other organizations that offer resources for researchers.

i. Representation of Underserved Populations
In many cancer clinical trials, specific patient populations are not appropriately represented, which limits the applicability of their results to the general public. The study linked to below sought to determine representation of ethnic minorities and women in cancer clinical trials.


ii. Geographic Barriers
Geographic location is another factor that can impact clinical trial accrual. Several studies, linked to below, have sought to examine how geographic distribution affects cancer outcomes and accessibility to clinical trials.


iii. Barriers to Enrolling Patients onto Clinical Trials
Although barriers to enrolling patients onto clinical trials has been the subject of many research studies, the low accrual rate among patients with cancer hasn’t changed much. The resources below provide insight on this problem and factors that may be impacting it.


iv. Broadening Eligibility Criteria

Eligibility criteria are vital for success and patient safety in clinical trials, but excessive criteria can affect trial accrual. Review the resources below to learn about current initiatives to broaden eligibility criteria.

• **Clinical Trial Eligibility Criteria.** American Society of Clinical Oncology – ASCO and Friends of Cancer Research began a partnership in 2016 to broaden eligibility criteria to make clinical trials more representative. Learn more about this initiative and the resulting publications.


v. Special Patient Populations

Special patient populations, including older adults, children, and people with disabilities, require attention to ensure inclusion in clinical trials. Review the below resources to learn about considerations for inclusion of special populations in clinical trials.


• U.S. Food and Drug Administration *Inclusion of Older Adults in Cancer Clinical Trial Draft Guidance for Industry* (Mar 2020)

• U.S. Food and Drug Administration *Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients* Guidance for Industry and IRBs (Jul 2020)


vi. Financial Barriers for Patients

There are many barriers to patient enrollment on clinical trials, with financial burden being an important factor. Check out the links below to learn about the reasons, including rising cost of cancer care and lack of transparency in coverage policy, and how to overcome them.


B. Patient Recruitment and Eligibility

The resources below will aid in developing strategies to improve and streamline recruitment and enrollment in your clinical trial program. Consider addressing barriers to patient participation, including language barriers, to increase number and diversity of patients included on trial.

- **Clinical Trials.** Cancer.net offers information and resources designed for patients about clinical trials. Refer to IX. Patient Resources for more resources from Cancer.net about clinical trials.
- Forte Research Patient recruitment in clinical trials: Steps to develop a successful enrollment strategy. 2017

C. Informed Consent Development, Implementation, and Documentation

- National Cancer Institute Describes Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials.
- The U.S. Department of Health and Human Services Informed Consent Checklist covers the basic elements of the informed consent process and documentation.
• **Informed Consent in Research.** This resource from the Ohio State University Center for Clinical and Translational Science provides an overview of the informed consent process and provides resources to facilitate the process.

• **Office of Human Research Protections: General informed consent requirements (Video).** This video from the U.S. Department of Health and Human Services uses case studies to explore common informed consent issues including capacity to consent, using a legally authorized representative, and meeting the regulatory requirements for the process of informed consent.

• **Patient Safety in Clinical Trials.** This Cancer.Net resource for patients addresses common questions related to safety in clinical trials.

**D. Patient Management While on Study and Long-term Follow-up**
(i.e., during treatment and protocol-specified shorter-term and long-term follow-up)

• **A Manual for Participants in Clinical Trials of Investigational Agents Sponsored by DCTC, NCI.** This manual from the Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) includes policies and procedures related to various elements of the development of new investigational agents.

• **Oncology Research Professional Manual.** This resource from SWOG provides strategies and helpful information, including templates, to facilitate long-term follow-up for study participants.

• **Subject Management and Site Activities.** This resource from the Ohio State University Center for Clinical and Translational Science provides information about key areas in managing study participants.

**E. Specimen Collection, Handling, Processing, Transporting and Destruction**

• **U.S. Food and Drug Administration Code of Federal Regulations**


• **Office for Human Research Protections Issues to Consider in the Research Use of Stored Data or Tissues.** This resource from the U.S. Department of Health and Human Services provides guidance around operating human cell repositories.


• **Biospecimen SOPs from NRG Oncology Manual of Operations and Standard Operating Procedures for the San Francisco Biospecimen Bank.** (PDF Download) This resource details the NRG Oncology Biospecimen Bank’s operations and includes helpful templates and sample documents.

**F. Protocol Deviation Reporting and Prevention**
(e.g., U.S. federal regulations, avoiding deviations)
• U.S. Food and Drug Administration 21 CFR Parts 312 and 316 – Expanded Access to Investigational Drugs for Treatment Use (Direct file download)
• University of Cincinnati How to Avoid Protocol Deviations (pages 108-129). This presentation provides an overview of protocol deviations, case studies, and steps for documentation and reporting.
• Noncompliance and Protocol Deviations (Direct file download). This presentation from Yale University covers noncompliance, reporting procedures, corrective and preventive action (CAPA) plans, and IRB action.
• National Cancer Institute Division of Cancer Prevention Standard Operating Procedure on Recording and Reporting Protocol Deviations

G. Emergency Use of an Investigational Drug or Biologic Agent
(e.g., U.S. federal policies, procedures)

• U.S. Food and Drug Administration Information Sheet: Treatment Use of Investigational Drugs
• U.S. Food and Drug Administration Investigational New Drug (IND) Application
• Mayo Clinic Human Research Protection Program Procedure for Emergency Single-Case Use of an Investigational Device, Drug or Biologic Product