CLINICAL RESEARCH

- **Is there a source for information on the preparation of clinical research grant applications?**

  The Center for Scientific Review (CSR) has developed a web site for Advice to Investigators Submitting Clinical Research Applications. The web site also contains links to policies and institute contacts.

  See Conducting Clinical Trials for links to NCI clinical trial resources.

- **Are there special initiatives to support clinical trials research?**

  Yes. See NCI Extramural Funding Opportunities for all initiatives. Specific initiatives to support clinical trials include Quick Trials for Novel Cancer Therapy and Prevention (R21) and Clinical Cancer Therapy and Prevention Research (R01).

- **Where can I find information on the policies applicable to human subjects research?**

  See Research Involving Human Subjects for information on the HHS and NIH requirements and resources for the extramural community involved in human subjects research.

  In addition, see link to Inclusion of Women and Minorities as Participants in Research Involving Human Subjects.

- **Where can I find information on the requirements for data and safety monitoring plans on NCI funded grants?**

  The essential elements required for a data safety and monitoring plan funded by the NCI can be found at the NCI Data Safety and Monitoring Guidelines link. In addition, examples of cancer center monitoring plans are provided.

- **What resources and programs are available to assist clinicians in carrying out clinical research ?**

  The Cancer Therapy Evaluation Program (CTEP) provides access to a wide variety of resources, including Clinical Investigator forms and electronic applications for the standardization of trial data collection and reporting, including common toxicity criteria and common data elements. The Investigator's Handbook provides information on the policies and procedures for participants in clinical trials of investigational agents sponsored by NCI. The Clinical Trials Support Unit (CTSU) allows physicians who are not affiliated with a cooperative group to enroll patients on NCI sponsored clinical trials.

  The Developmental Therapeutics Program provides drug discovery and development services through such programs as Rapid Access to Intervention Development (RAID) for production of drugs and biologics and anti-cancer compound screening services using in vivo and in vitro models.

  Contact the Division of Cancer Prevention for information on prevention clinical trials. Contact the Division of Cancer Control and Population Sciences for information on behavior, clinical epidemiology and genetics, survivorship, and outcomes research.

The Cancer Biomedical Informatics Grid (caBIG™) is developing a comprehensive set of clinical trials management tools including an adverse event reporting module, a clinical trials participant registry, a clinical data exchange system and a patient study calendar.

Visit the NCI Clinical Trials web site for information on NCI sponsored clinical trials, clinical trial results, and education materials.

- **How can a physician not affiliated with a cooperative group participate in NCI phase III clinical trials?**

  The Clinical Trials Support Unit (CTSU) is a project sponsored by the NCI for the support of a national network of physicians to participate in NCI-sponsored Phase III cancer treatment trials. More information is provided on https://www.ctsu.org/.

- **How can primary care physicians become involved in primary and secondary prevention studies?**

  The Community Clinical Oncology Program (CCOP) supports a network linking academic institutions with community medical practitioners for conducting cancer prevention and treatment clinical trials. Primary care physicians are encouraged to become involved with their local CCOP program.

  The National Cancer Institute Community Cancer Centers Program (NCCCP) is designed to encourage the collaboration of private-practice medical, surgical, and radiation oncologists with NCI supported cancer centers to provide state of the art cancer care and prevention.

- **Should the NCI support the development of clinical trial management tools that would allow researchers to access and use data to consider individual treatment, new trial designs, etc.?**

  This issue was addressed in the Clinical Trials Working Group report published in 2005. In response to the report, the Cancer Biomedical Informatics Grid (caBIG™) is developing a comprehensive set of modular, interoperable and standards-based tools designed to meet clinical trials management needs. Examples of these tools include an adverse event reporting module, a clinical trials participant registry, a patient study calendar, and a lab information exchange module and may be viewed at the Clinical Trials Management Systems (CTMS) Workspace. In Addition, the Coordinating Center for Clinical Trials is leading the effort to establish a comprehensive database containing information on all NCI-funded clinical trials to facilitate better planning and management across clinical trial venues.

- **Since physicians are not aware of many clinical trials, are there marketing tools to assist physicians and patients?**

  The NCI Clinical Trials web site provides information on clinical trials, trial results, and education materials. The PDQ (Physician Data Query) is NCI's comprehensive cancer database on active clinical trials and includes peer-reviewed summaries. Clinical trials information on all NIH sponsored clinical trials can be accessed through the web site, clinicaltrials.gov.

  The Cancer Information Service (CIS) educates the public about cancer prevention, risk factors, symptoms, diagnosis, treatment, and research. Fact Sheets are available at the CIS web site and cancer information specialists will answer questions at 1-800-4-CANCER. See the NCI Publications Locator to view and order NCI publications.

The Clinical Trial Education Series (CTES) is a group of thirteen different educational materials (books, booklets, slides, videos) to target education and outreach for health professionals and patients.

The Cancer Biomedical Informatics Grid (caBIG™) is developing a comprehensive set of clinical trials management tools including an adverse event reporting module, a clinical trials participant registry, a clinical data exchange system and a patient study calendar.

- **Are NCI supported human specimen banks available to investigators?**

  Yes. The Specimen Resource Locator is a database to help researchers locate human specimens (tissue, serum, DNA/RNA, other specimens) for cancer research. It includes tissue banks and tissue procurement systems with access to normal, benign precancerous and cancerous human tissue from a variety of organs.

  In addition, the Office of Biorepositories and Biospecimen Research (OBBR) was established in 2005 to guide, coordinate, and develop the NCI's biospecimen resources and capabilities. OBBR activities include, establishment of the Biospecimen Research Network and the Biospecimen Research Database, development of NCI Best Practices for Biospecimen Resources, and sponsoring a series of Biospeciman Best Practices Forums.

  The Cancer Biomedical Informatics Grid (caBIG™) has developed tissue bank repository tools and supports the Shared Biospecimen Data Directory.

  Contact staff in the Office of Biorepositories and Biospecimen Research or Cancer Diagnosis Program for more information.

- **Can NIH help me protect the confidentiality of my research subjects?**

  Yes, with a certificate of confidentiality. See NIH's Certificates of Confidentiality Kiosk for details and follow instructions on applying for the certificate.

- **Can NCI help pay for costs related to the privacy rule?**

  Yes. You can discuss privacy rule issues in the Research Plan of your grant application and budget (for grants or cooperative agreements) or technical and business proposal (for contracts).

- **Do NIH grantees and contractors have ethical requirements for human subjects?**

  Yes. See the Regulations, Policies & Guidance Ethical Guidelines & Regulations for ethical guidelines and federal regulations on the protection of human subjects. In addition, see guidance on Research Involving Vulnerable Populations.

- **When is a clinical trial required to be registered on ClinicalTrials.gov?**

  Public Law 110-85 (also known as the FDA Amendments Act), includes a requirement that if an "applicable clinical trial" is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, any grant or progress report shall include a certification that the responsible party has made all required submissions for the applicable trial to ClinicalTrials.gov. Under the statute, the "applicable clinical trials" trials generally include:

  (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1

investigations, of a product subject to FDA regulation;

(2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.

See Clinical Trials Registration in Clinicaltrials.gov for more information on the requirements and process.

According to the NCI Clinical Trials Reporting Program (CTRP), an upgraded set of reporting requirements will apply to clinical trials receiving funding from any grant mechanism or contract beginning in January 2009.

- **What are NCI's future plans in the area of clinical trials and translational research?**

  The Clinical Trials Working Group (CTWG) was established in January, 2004, to advise NCI on issues concerning NCI-supported cancer clinical trials. An extramural advisory committee, the Clinical Trials Advisory Committee (CTAC), oversees the implementation of the recommendations of the CTWG. Contact Coordinating Center for Clinical Trials (CCCT) for more information.

  The Translational Research Working Group (TRWG) was established in 2005 to develop recommendations about how the NCI can best organize its investment to further "translational research." Go to TRWG web site.

- **How do patient advocates participate in NCI's research activities and programs?**

  The NCI has established the Consumer Advocates in Research and Related Activities (CARRA) program within the Office of Advocacy Relations (OAR). The CARRA program was created to integrate the perspective of people affected by cancer into a wide range of NCI's programs and activities, including peer review of clinical research. See CARRA web page for more information.

- **How do I locate NCI staff involved in clinical research?**

  For treatment trials, go to the Cancer Therapy Evaluation Program for therapeutic trials, Radiation Research Program for radiation trials, and Cancer Imaging Program for imaging trials.

  For cancer prevention trials, go to Community Clinical Oncology Program.

  For cancer control and population research, including behavioral and outcomes research, go to the Division of Cancer Control and Population Sciences.