

Yesterday

- Hippocrates, the father of modern medicine, conducted what is now considered clinical research through his carefully documented clinical observations. He wasn't the first. There's evidence of clinical research in the Old Testament and among the ancient Chinese, Hindus and numerous other cultures.
- Researchers in the 19th century made remarkable strides in medical discovery amid growing acknowledgement that research participants should be informed about and give permission for their involvement. In the 20th century, patient protections gradually were strengthened.
- In 1953, the Clinical Center (CC) opened on the Bethesda, Maryland, campus. It was a self-contained community of clinicians, scientists, patients, and support staff, with the common goal of conquering both chronic and acute disease.
- Since the beginning, NIH's "Guiding Principles in Medical Research Involving Humans" required prior review and the participant's informed consent. This was an early version of the Institutional Review Board mandated in 1966 by the US Surgeon General for all Public Health Service grants involving human subjects.
- Milestones in medical discovery were made thanks to the more than 350,000 volunteers from around the world and all walks of life who have participated in research at the NIH CC.
- Groundbreaking treatments and procedures pioneered at the NIH CC include:
 - chemotherapy, initially targeting choriocarcinoma, and later treating childhood leukemia and Hodgkin's disease
 - artificial mitral heart valve replacement surgery
 - use of immunotherapy to treat cancer (melanoma)
 - treatment of AIDS with AZT
 - gene therapy
 - controlled trials of lithium's effect on depression
 - immunosuppressive therapy for nonmalignant diseases such as in lupus, Wegener's granulomatosis, and midline granuloma (a small mass of granulation tissue caused by chronic infection)
 - a computerized hospital information system to facilitate clinical research
 - development of blood screening tests for AIDS and hepatitis that have made for a safer blood supply

Today

- The NIH CC in Bethesda, Maryland, is the world's largest hospital dedicated totally to clinical research.
- The new hospital, the Mark O. Hatfield Clinical Research Center, opened in 2004.
- There are about 1,500 clinical research protocols under way; most are clinical trials testing new treatments and natural history studies. Most studies are early trials, Phase 1 and 2.
- The number of principal investigators now totals 505, up from 487 in FY05. In 2006, there were 6,096 admissions and 95,151 outpatient visits.
- Research collaborations have expanded to include extramural partners through the Bench-to-Bedside awards program, designed to speed translation of promising laboratory discoveries into better medical treatments.
- The hospital's Clinical Research Information System supports patient care and clinical research data collection.
- The Web-based application ProtoType, designed at the CC, is a protocol writing tool that streamlines and facilitates the process of moving a research idea into implementation.

Tomorrow

- The focus of the CC's clinical research will shift from treating chronic diseases to predicting illness before it occurs and personalizing therapies.
- The CC will continue to adapt physically to evolving research needs because of its unique design flexibility.
- The CC will continue to be on the leading edge of the NIH Roadmap for Medical Research's efforts in re-engineering the clinical research enterprise and will be a major resource in the Clinical and Translational Science Award Program consortium.
- Collaborations with research partners outside NIH will continue to be pursued through the Bench-to-Bedside awards program and extramural researchers will have opportunities for access to the CC's unique resources.
- Informatics tools developed at the CC will be refined and available for use and adaptation by extramural researchers. The Clinical Research Information System's next phase will be a data mart that will pool data and text for use by intramural researchers. A repository will allow data sharing with extramural investigators.

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