

米国 Clinical Research Enhancement Act

公的研究費にもとづく臨床研究環境整備をうたった

Public Law 106-505
106th Congress

An Act

Nov. 13, 2000
[H.R. 2498]

To amend the Public Health Service Act to provide for recon-
Secretary of Health and Human Services regarding the plac
external defibrillators in Federal buildings in order to imp
of individuals who experience cardiac arrest in such buildings, and to establish
protections from civil liability arising from the emergency use of the devices.

2000年11月

Public Health
Improvement
Act.
42 USC 201 note.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Public Health
Improvement Act”.

(b) TABLE OF CONTENTS.—The table of contents of this Act
is as follows:

NIHによる臨床研究助成の振興内容を細かく規定

Sec. 101. Short title.

Sec. 102. Amendments to the Public Health Service Act.

TITLE II—CLINICAL RESEARCH ENHANCEMENT

Sec. 201. Short title.

Sec. 202. Findings and purpose.

Sec. 203. Increasing the involvement of the National Institutes of Health in clinical
research.

Sec. 204. General clinical research centers.

Sec. 205. Loan repayment program regarding clinical researchers.

Sec. 206. Definition.

Sec. 207. Oversight by General Accounting Office.

<http://www.fda.gov/cder/about/smallbiz/faq.htm#Types%20of%20INDs>

Types of INDs

An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.

Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR, Sec. 312.23 or Sec. 312.34. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.

Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are two IND categories:

- **Commercial.** These are applications that are submitted primarily by companies whose ultimate goal is to obtain marketing approval for a new product.
- **Research (non-commercial)**

Emergency and Treatment INDs are also known as "Compassionate" INDs, but the term "Compassionate" is not in the IND regulations.

http://www.cms.hhs.gov/ClinicalTrialPolicies/

Overview - Microsoft Internet Explorer

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Medicare Clinical Trial Policies

Overview

Overview

Clinical trials are research studies designed to evaluate the safety and effectiveness of medical care. They are key to understanding the appropriate use of medical interventions of all types and informing payers about what services to cover. Previously, Medicare has not paid for items and services related to clinical trials because of their experimental nature. As a result, only a very small percentage of American seniors participate in clinical trials, although the elderly bear a disproportionate burden of disease in the United States.

2000年9月から本格導入

ted States issued an executive memorandum directing the Secretary to authorize [Medicare] payment for routine patient care costs...and ated with participation in clinical trials." In keeping with the refining the routine costs of clinical trials and identifying the clinical trials for which payment for such routine costs should be made.

Downloads

[Proposed National Coverage Decision \(PDF, 481KB\)](#)

[Final National Coverage Decision \(PDF, 311KB\)](#)

[Program Memorandum \(PDF, 10.91KB\)](#)

[Provider Bulletin \(PDF, 67KB\)](#)

[Federal Register Notice Announcing 10/20/00 Meeting \(PDF, 127KB\)](#)

[Federal Register Notice Announcing 11/20/00 Meeting \(PDF, 138KB\)](#)

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公的助成を受けている
臨床試験における通常診療経費は保険診療とする

どのような臨床試験が対象となるのか

▪ Deemed Trials.

Some trials are considered automatically deemed as having desirable characteristics. They include:

Effective September 19, 2000

- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DOD), and Department of Veterans Affairs (VA);
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
- Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration (FDA);

etc

Medicare Coverage Clinical Trial Program Memorandum