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 place external defibrillators in Federal buildings in order to import of individuals who experience cardiac arrest in such buildings, and to establish protections from civil liability arising from the emergency use of the devices.

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. Snort 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%21

Lypes of INDs

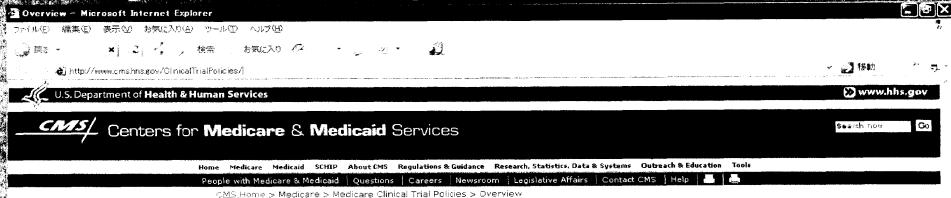
- An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might subsequently a research IND to propose studying an unapproved drug, or an approve product for 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 IND in accordance with 21CFR, Sec. 312.23 or Sec. 312.34. It is also use for patients who do not meet the criteria of an existing study protocol, or 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 with 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
the term "Compassionate" is not in the IND regulations.

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



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 y authorize [Medicare] payment for routine patient care costs...and ated with participation in clinical trials." In keeping with the efining the routine costs of clinical trials and identifing the clinical bosts should be made.

Downloads

Proposed National Coverage Decision (PDF, 49/18)

Final National Coverage Decision (PDF_)1rB)

Program Memorandum (PDF, 105) 8)

Provider Bulletin (PDF 578B)

Sederal Redistan Natice Announcing 19/20/00 Meeting (PDS, 197KB)

Federal Register Notice Announcing 11/20/00 Meeting (PDF, 128/8)

Rolatod Linke Incido CMS

Browse By Audience

Provider Center Partner Center

Show More

ORGH TOLE

Browse By Subject

Medicane Coverace | American Indian/Alastic Native

Show More

公的助成を受けている 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が

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), Agen
 for Healthcare Research and Quality (AHRQ), CMS,
 Department of Defense (DOD), and Department of Vetera
 Affairs (VA);
- Trials supported by centers or cooperative groups that an funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
- Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drugs Administration (FDA);

etc

Medicare Coverage Clinical Trial Program Memoral