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

To amend the Public Health Service Act to provide for recon[illegible] Secretary of Health and Human Services regarding the plac[illegible] external defibrillators in Federal buildings in order to imp[illegible] 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

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

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

Public Health Improvement Act.
42 USC 201 note.

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

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

Types of INDs

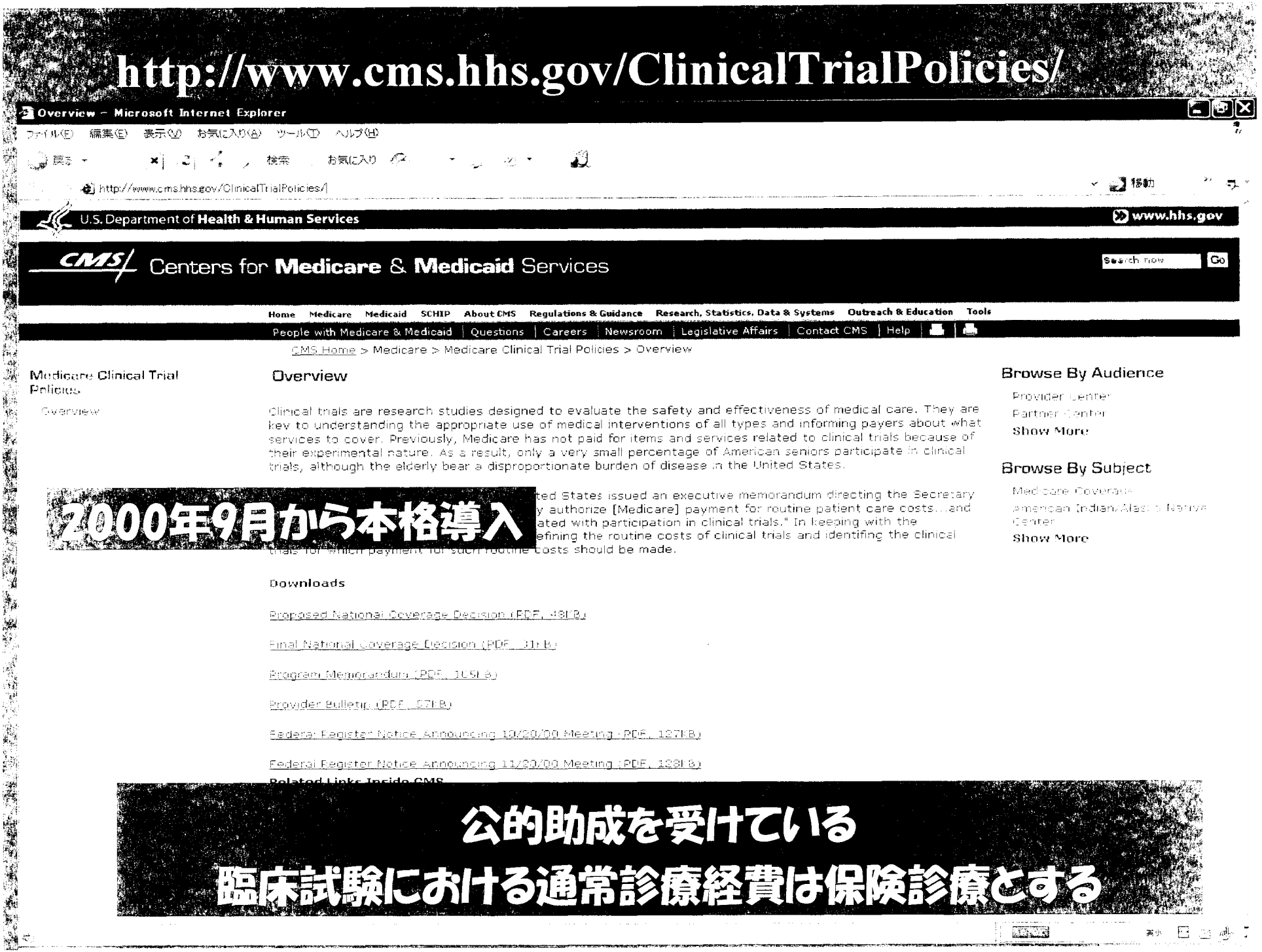
- An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might sub... a research IND to propose studying an unapproved drug, or an approved product for a new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



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 Drugs Administration (FDA);**
    - **etc**

Medicare Coverage Clinical Trial Program Memorandum