HR 4697

Human Research Subject Protections Act of 2002

Congress: 107 (2001–2003, Ended)
Chamber: House
Policy Area: Health
Introduced: May 9, 2002
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (May 17, 2002)
Official Text: https://www.congress.gov/bill/107th-congress/house-bill/4697

Sponsor

Name: Rep. DeGette, Diana [D-CO-1]
Party: Democratic • **State:** CO • **Chamber:** House

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Greenwood, James C. [R-PA-8]	R · PA		May 9, 2002
Rep. Brown, Sherrod [D-OH-13]	D · OH		Jul 18, 2002
Rep. Foley, Mark [R-FL-16]	R · FL		Jul 18, 2002

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 17, 2002

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 9, 2002)

Human Research Subject Protections Act of 2002 - Amends the Public Health Service Act to require all human subject research conducted, supported or otherwise subject to Federal regulation to be conducted in accordance with the common rule and the vulnerable-population rules, as set forth in the Code of Federal Regulations. Defines such terms according to different regulations for human subject research subject to the Federal Food, Drug, and Cosmetic Act.

Requires the Secretary of Health and Human Services to review all such regulations to harmonize them where feasible with a subsequent proposed rule, explaining remaining differences.

Sets forth the authority of the Secretary to modify regulations.

Requires informed consent, as specified.

Requires an Institutional Review Board to approve all human subject research proposals.

Directs the Secretary to establish criteria for identifying and monitoring high risk clinical trials.

Prohibits the use of Federal funds for classified human subject research, as specified.

Requires the Secretary to determine whether an entity has violated these requirements, as specified.

Establishes an Office of Human Research Protections within the Office of the Secretary to make grants, conduct research and Institutional Review Board audits (requiring corrective action if necessary), and coordinate Federal efforts. Requires the Director to notify the relevant regulatory agency if deficiencies are found.

Authorizes the Director of such Office to make grants for the development of a model education program.

Requires coordination with the Commissioner of Food and Drugs.

Continues the National Research Protections Act Advisory Committee.

Requires the Secretary to promulgate regulations addressing the participation of people with diminished decisionmaking capacity in human subject research.

Actions Timeline

- **May 17, 2002:** Referred to the Subcommittee on Health.
- **May 9, 2002:** Introduced in House
- **May 9, 2002:** Introduced in House
- **May 9, 2002:** Referred to the House Committee on Energy and Commerce.