

## HR 1715

### Protection for Participants in Research Act of 2009

**Congress:** 111 (2009–2011, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Mar 25, 2009

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (Mar 26, 2009)

**Official Text:** <https://www.congress.gov/bill/111th-congress/house-bill/1715>

## Sponsor

**Name:** Rep. DeGette, Diana [D-CO-1]

**Party:** Democratic • **State:** CO • **Chamber:** House

## Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Mar 30, 2009
Rep. Doggett, Lloyd [D-TX-25]	D · TX		Mar 30, 2009

## Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 26, 2009

## Subjects & Policy Tags

### Policy Area:

Health

## Related Bills

No related bills are listed.

Protection for Participants in Research Act of 2009 - 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.

Requires the Secretary of Health and Human Services to review and harmonize such regulations.

Requires informed consent before an individual may be a subject of human research.

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

Directs the Secretary to establish criteria for determining whether a human subject research project must be conducted in accordance with a data safety and monitoring plan.

Prohibits grants or awards to a public entity or private academic institution that does not have a program to educate investigators and Board members on the protection of human research subjects.

Prohibits the use of federal funds for classified human subject research if: (1) the Board has waived the informed consent requirement; or (2) the research is exempt from Board review.

Establishes the Office of Human Research Protections within the Office of the Secretary. Requires the Director of the Office to: (1) provide for the protection of human research subjects; (2) establish criteria regarding assurance of compliance with Common Rule requirements; and (3) coordinate federal activities with respect to the protection of human research subjects. Authorizes the Director to make grants for a model education program.

Requires the Secretary to: (1) promulgate regulations enhancing the protection of people with diminished decision-making capacity participating in human subject research; and (2) study whether the number of certain members of Institutional Review Boards should be increased.

## **Actions Timeline**

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- **Mar 26, 2009:** Referred to the Subcommittee on Health.
- **Mar 25, 2009:** Introduced in House
- **Mar 25, 2009:** Referred to the House Committee on Energy and Commerce.