



Sen. Julie A. Morrison

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10300HB5405sam001

LRB103 37925 LNS 73018 a

1 AMENDMENT TO HOUSE BILL 5405

2 AMENDMENT NO. _____. Amend House Bill 5405 by replacing
3 everything after the enacting clause with the following:

4 "Section 5. The Department of Public Health Powers and
5 Duties Law of the Civil Administrative Code of Illinois is
6 amended by adding Section 2310-730 as follows:

7 (20 ILCS 2310/2310-730 new)

8 Sec. 2310-730. Diversity in clinical trials.

9 (a) As used in this Section, "underrepresented community"
10 or "underrepresented demographic group" means a community or
11 demographic group that is more likely to be historically
12 marginalized and less likely to be included in research and
13 clinical trials represented by race, ethnicity, sex, sexual
14 orientation, socioeconomic status, age, and geographic
15 location.

16 (b) Any State entity or hospital that receives funding

1 from the National Institutes of Health for the purpose of
2 conducting clinical trials of drugs or medical devices is
3 required to:

4 (1) adopt a policy that will result in the
5 identification and recruitment of persons who are members
6 of underrepresented demographic groups to participate in
7 the clinical trials and that:

8 (A) includes specific strategies for trial
9 enrollment and retention of diverse participants,
10 including, but not limited to, site location and
11 access, sustained community engagement, and reducing
12 burdens due to trial design or conduct, as
13 appropriate; and

14 (B) uses strategies recommended by the United
15 States Food and Drug Administration to identify and
16 recruit those persons to participate in the clinical
17 trials;

18 (2) provide information to trial participants in
19 languages other than English in accordance with current
20 federal requirements;

21 (3) provide translation services or bilingual staff
22 for trial recruitment and consent processes;

23 (4) provide culturally specific recruitment materials
24 alongside general enrollment materials; and

25 (5) provide remote consent options when not prohibited
26 by the granting entity or federal regulations.

1 (c) The Department, through voluntary reporting from
2 research institutions and in consultation with community-based
3 organizations and other stakeholders as appropriate and
4 available, shall analyze and provide recommendations on the
5 following:

6 (1) the demographic groups and populations that are
7 currently represented and underrepresented in clinical
8 trials in Illinois, including representation of groups
9 based on their geographic location;

10 (2) the barriers that prevent persons who are members
11 of underrepresented demographic groups from participating
12 in clinical trials in Illinois, including barriers related
13 to transportation; and

14 (3) approaches for how clinical trials can
15 successfully partner with community-based organizations
16 and others to provide outreach to underrepresented
17 communities.

18 By July 1, 2026, the Department shall issue a report and
19 post on its website the results of the analysis required under
20 this subsection and any recommendations to increase diversity
21 and reduce barriers for participants in clinical trials.

22 (d) The Department shall review the most recent guidance
23 on race and ethnicity data collection in clinical trials
24 published by the United States Food and Drug Administration
25 and establish, using existing infrastructure and tools an
26 Internet website that:

1 (1) provides information concerning methods recognized
2 by the United States Food and Drug Administration for
3 identifying and recruiting persons who are members of
4 underrepresented demographic groups to participate in
5 clinical trials; and

6 (2) contains links to Internet websites maintained by
7 medical facilities, health authorities and other local
8 governmental entities, nonprofit organizations, and
9 scientific investigators and institutions that are
10 performing research relating to drugs or medical devices
11 in this State.

12 The Department may apply for grants from any source,
13 including, without limitation, the Federal Government, to fund
14 the requirements of this Section."