

STATE OF NEW YORK

9331

IN ASSEMBLY

February 23, 2022

Introduced by M. of A. SOLAGES -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to requiring clinical trials that apply for state grant funding to make certain information about such clinical trials public

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Article 2 of the public health law is amended by adding a
2 new title 8 to read as follows:

TITLE 8

CLINICAL TRIALS

Section 269. Definitions.

269-a. Grant requirements.

269-b. Posting requirements.

§ 269. Definitions. For purposes of this title:

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9 1. "clinical trial" shall have the same meaning as set forth in subdivision two-b of section forty-nine hundred of this chapter.

10 2. "health care provider" shall mean a practitioner in an individual
11 practice, group practice, partnership, professional corporation or other
12 authorized form of association, a hospital or other health care institution
13 issued an operating certificate pursuant to this chapter or the
14 mental hygiene law, a certified home health agency or a licensed home
15 care services agency, and any other purveyor of health or health related
16 items or services including but not limited to a clinical laboratory, a
17 physiological laboratory, a pharmacy, a purveyor of x-ray or imaging
18 services, a purveyor of physical therapy services, a purveyor of health
19 or health related supplies, appliances or equipment, or an ambulance
20 service.

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22 § 269-a. Grant requirements. 1. Following the effective date of this
23 section, the commissioner shall require any sponsor of a clinical trial
24 in this state, including but not limited to, a pharmaceutical drug
25 manufacturer, pharmaceutical drug wholesaler, academic medical center,
26 voluntary group, federal agency or health care provider, that applies
27 for a state grant to conduct such clinical trial, to conspicuously post

EXPLANATION--Matter in italics (underscored) is new; matter in brackets [-] is old law to be omitted.

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1 certain information about such clinical trial on the department's
2 website.

3 2. To the extent disclosure is permitted under federal law, the infor-
4 mation posted in accordance with subdivision one of this section shall
5 include, but shall not be limited to, the following:

6 (a) the name of all clinical trial sponsors, funders and manufactur-
7 ers, including the name and contact information, as well as the institu-
8 tional affiliation, of all sponsors, co-sponsors and administrators;

9 (b) a summary of the purpose of the clinical trial, including, but not
10 limited to: (i) the name of the pharmaceutical drug being tested and its
11 active ingredients, if applicable; (ii) the type of clinical trial to be
12 conducted; (iii) the overall design of the study, including the statis-
13 tical method to be employed; (iv) the status or phase type of the trial;
14 (v) the inclusion and exclusion criteria; (vi) the treatment methods
15 used; (vii) all hypotheses tested by the trial; and (viii) the medical
16 condition or conditions being studied;

17 (c) the start date and end date of the clinical trial; and

18 (d) information pertaining to the clinical trial, including, but not
19 limited to potential adverse effects of the pharmaceutical drug or
20 biological product associated with the clinical trial.

21 3. The commissioner shall promulgate rules and regulations as deemed
22 necessary to aid in the collection and posting of the clinical trial
23 information required pursuant to this section and shall monitor the
24 department's website for compliance with the requirements of this
25 section.

26 § 269-b. Posting requirements. 1. Following the effective date of this
27 section, the commissioner shall require any health care provider offer-
28 ing a clinical trial in this state to conspicuously post certain infor-
29 mation about such clinical trial on their website.

30 2. To the extent disclosure is permitted under federal law, the infor-
31 mation posted in accordance with subdivision one of this section shall
32 include, but shall not be limited to, the following:

33 (a) the therapeutic intent of the clinical trial;

34 (b) the name of all clinical trial sponsors, funders and manufactur-
35 ers, including the name and contact information, as well as the institu-
36 tional affiliation, of all sponsors, co-sponsors and administrators;

37 (c) a summary of the purpose of the clinical trial, including, but not
38 limited to: (i) the name of the pharmaceutical drug being tested and its
39 active ingredients, if applicable; (ii) the type of clinical trial to be
40 conducted; (iii) the overall design of the study, including the statis-
41 tical method to be employed; (iv) the status or phase type of the trial;
42 (v) the inclusion and exclusion criteria; (vi) the treatment methods
43 used; (vii) all hypotheses tested by the trial; and (viii) the medical
44 condition or conditions being studied;

45 (d) the start date and end date of the clinical trial; and

46 (e) information pertaining to the clinical trial, including, but not
47 limited to potential adverse effects associated with the clinical trial.

48 § 2. This act shall take effect immediately.