

SENATE No. 1906

The Commonwealth of Massachusetts

SENATE, May 19, 1975.

The committee on Health Care, to whom was referred the petition (accompanied by bill, House, No. 3855) of Charles F. Flaherty, Jr., Chester G. Atkins and Melvin H. King that the Department of Public Health be authorized to create a central registry of human research projects on human subjects reports the accompanying bill (Senate, No. 1906).

For the Committee,

CHESTER G. ATKINS

The Commonwealth of Massachusetts

In the Year One Thousand Nine Hundred and Seventy-Five.

AN ACT CREATING A CENTRAL REGISTRY OF RESEARCH PROJECTS ON HUMAN SUBJECTS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Chapter 17 of the General Laws is hereby amended by insert-
2 ing after Section 4 A the following new section: —

3 *Section 4B.* For the purposes of this section, the word
4 “research” shall be defined as any investigation involving the
5 biological, behavioral, or psychological study of a human
6 being, his body, or surroundings, including, but not limited to
7 any medical or surgical procedure, any withdrawal or removal
8 of body tissue or fluid, any administration of a chemical sub-
9 stance, any deviation of normal diet or daily regimen, and any
10 manipulation or observation of bodily processes, behavior, or
11 environment; and the word “institution” shall be defined as any
12 facility for the care of unwed mothers, hospital, clinic, infirm-
13 ary maintained in a town, convalescent or nursing home, rest
14 home or charitable home for the aged licensed or subject to
15 licensure pursuant to Chapter 111; any state hospital operated
16 by the department of public health; any facility as defined in
17 Section 1 of Chapter 111B; any private, county, or municipal
18 facility, department or ward which is licensed or subject to
19 licensure by the department of mental health pursuant to
20 Section 29 of Chapter 19; any facility as defined in Section 1
21 of Chapter 123; any facility as defined in Section 38 of Chap-
22 ter 123; the Soldiers’ Home in Holyoke; and the Soldiers’
23 Home in Massachusetts.

24 The department shall establish and maintain a registry of
25 research protocols and projects in progress on or after
26 September first, nineteen hundred and seventy-five, or on such
27 date as final regulations adopted under the provisions of this
28 Section are promulgated, which involve research conducted on
29 human subjects who are legal residents of, or reside in, the

30 Commonwealth.

31 Such registry shall pertain to protocols and projects under-
32 taken by persons through or in conjunction with any institu-
33 tion hereinabove defined, or involving research techniques
34 conducted on persons under the auspices of, or in conjunction
35 with, or through the cooperation of any such institution.

36 The department shall promulgate regulations governing
37 information maintained in the registry which shall include, but
38 need not be limited to the following: —

39 (a) the name, business address, and professional and organi-
40 zational affiliation of the researcher(s); and

41 (b) the name, address, and related identification of the
42 funding source(s) including the amount of funding, duration
43 of the project, and date of commencement; and

44 (c) a copy of the research protocol, including a thorough
45 description of the project, its purposes, the age, sex, race, and
46 related information on anticipated subjects, the number of
47 subjects and what will be done to them, the anticipated results,
48 and a description of how the researchers will obtain the in-
49 formed and voluntary consent of the subjects, and, in the
50 instances of minor subjects, their parents.

The following is a list of the names of the persons who have been admitted to the membership of the Society since the last meeting. The names are arranged in alphabetical order of their surnames.

Mr. J. A. Smith
 Mr. W. B. Jones
 Mr. C. D. Brown
 Mr. E. F. Green
 Mr. G. H. White
 Mr. I. K. Black
 Mr. L. M. Grey
 Mr. N. O. Blue
 Mr. P. Q. Red
 Mr. R. S. Yellow
 Mr. T. U. Purple
 Mr. V. W. Pink
 Mr. X. Y. Orange
 Mr. Z. A. Silver
 Mr. B. C. Gold
 Mr. D. E. Bronze
 Mr. F. G. Iron
 Mr. H. I. Steel
 Mr. J. K. Lead
 Mr. L. M. Tin
 Mr. N. O. Zinc
 Mr. P. Q. Copper
 Mr. R. S. Nickel
 Mr. T. U. Platinum
 Mr. V. W. Palladium
 Mr. X. Y. Silver
 Mr. Z. A. Gold