



CONFIDENTIALITY CERTIFICATE

issued to

Employees of

Children's Hospital and Regional Medical Center

and Other Participants

conducting research known as

SEARCH FOR DIABETES IN YOUTH, PHASE 2 (SEARCH Phase 2)
Cooperative Agreement No. 5-U01-DP-000244-02

In accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)) this certificate is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research.

Under authority vested in the Secretary of Health and Human Services under that section, all persons who –

- (1) are employed by Children's Hospital and Regional Medical Center, and its contractors and cooperating agencies; and
- (2) have, in the course of that employment, access to the information which would identify individuals who are the subjects of a research project entitled "SEARCH for Diabetes in Youth, Phase 2"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research, with the exceptions and limitations set forth below.

The purpose of SEARCH Phase 2 is to build on SEARCH Phase 1 which assessed the burden of diabetes with onset in childhood and adolescence in the U.S. SEARCH Phase 2 will enhance the understanding of the natural history, complications, and risk factors of diabetes mellitus with the onset in childhood and adolescence.

As provided in section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)),

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

The following conditions apply to the protection provided under this certificate:

- (1) This certificate does not authorize Children's Hospital and Regional Medical Center, and its contractors or cooperating agencies to refuse to reveal identifying information concerning research subjects if any of the following conditions exist:
 - (a) The subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of identifying information.
 - (b) Authorized personnel of the United States Department of Health and Human Services request such information for audit or program evaluation of the research project, or for investigation of Children's Hospital and Regional Medical Center, and its contractors or cooperating agencies in carrying out the research project.
 - (c) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) or regulations promulgated there under (Title 21, Code of Federal Regulations).
- (2) This certificate requires that there be no disclosures of identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects, except as provided for in paragraph (1) above.
- (3) The confidentiality certificate does not govern the voluntary disclosure of identifying characteristics of research subjects.
- (4) This certificate does not represent an endorsement of the research project by the Department of Health and Human Services.
- (5) All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection.

- (6) This certificate is effective upon issuance, and will expire at the end of October 2011, or sooner if the holder is notified of cancellation in accordance with the procedures set out in 42 C.F.R. § 2a.8. The protection afforded by this certificate of confidentiality is permanent (including after death) for persons who participated as subjects in the research during any time the certificate was in effect.

Date: 10/18/06



James W. Stephens, Ph.D.

Acting Associate Director for Science, CDC



CONFIDENTIALITY CERTIFICATE

issued to

Employees of

Children's Hospital Medical Center

and Other Participants

conducting research known as

SEARCH FOR DIABETES IN YOUTH
Cooperative Agreement No. 5-U01-DP-000248-02

In accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)) this certificate is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research.

Under authority vested in the Secretary of Health and Human Services under that section, all persons who –

- (1) are employed by Children's Hospital Medical Center, and its contractors and cooperating agencies; and
- (2) have, in the course of that employment, access to the information which would identify individuals who are the subjects of a research project entitled "SEARCH for Diabetes in Youth, Phase 2"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research, with the exceptions and limitations set forth below.

The purpose of SEARCH Phase 2 is to build on SEARCH Phase 1 which assessed the burden of diabetes with onset in childhood and adolescence in the U.S. SEARCH Phase 2 will enhance the understanding of the natural history, complications, and risk factors of diabetes mellitus with onset in childhood and adolescence.

As provided in section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)),

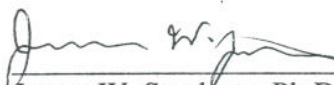
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

The following conditions apply to the protection provided under this certificate:

- (1) This certificate does not authorize Children's Hospital Medical Center, and its contractors or cooperating agencies to refuse to reveal identifying information concerning research subjects if any of the following conditions exist:
 - (a) The subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of identifying information.
 - (b) Authorized personnel of the United States Department of Health and Human Services request such information for audit or program evaluation of the research project, or for investigation of Children's Hospital Medical Center, and its contractors or cooperating agencies in carrying out the research project.
 - (c) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) or regulations promulgated there under (Title 21, Code of Federal Regulations).
- (2) This certificate requires that there be no disclosures of identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects, except as provided for in paragraph (1) above.
- (3) The confidentiality certificate does not govern the voluntary disclosure of identifying characteristics of research subjects.
- (4) This certificate does not represent an endorsement of the research project by the Department of Health and Human Services.
- (5) All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection.

- (6) This certificate is effective upon issuance, and will expire at the end of October 2011, or sooner if the holder is notified of cancellation in accordance with the procedures set out in 42 C.F.R. § 2a.8. The protection afforded by this certificate of confidentiality is permanent (including after death) for persons who participated as subjects in the research during any time the certificate was in effect.

Date: 10/18/06



James W. Stephens, Ph.D.
Acting Associate Director for Science, CDC



CONFIDENTIALITY CERTIFICATE

issued to

Employees of

Kaiser Permanente Southern California

and Other Participants

conducting research known as

SEARCH FOR DIABETES IN YOUTH, PHASE 2 (SEARCH PHASE 2)
Cooperative Agreement No. 5-U01-DP-000246-02

In accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)) this certificate is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research.

Under authority vested in the Secretary of Health and Human Services under that section, all persons who –

- (1) are employed by Kaiser Permanente Southern California, and its contractors and cooperating agencies; and
- (2) have, in the course of that employment, access to the information which would identify individuals who are the subjects of a research project entitled "SEARCH for Diabetes in Youth, Phase 2"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research, with the exceptions and limitations set forth below.

The purpose of SEARCH Phase 2 is to build on SEARCH Phase 1 which assessed the burden of diabetes with onset in childhood and adolescence in the U.S. SEARCH Phase 2 will enhance the understanding of the natural history, complications, and risk factors of diabetes mellitus with onset in childhood and adolescence.

As provided in section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)),


"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

The following conditions apply to the protection provided under this certificate:

- (1) This certificate does not authorize Kaiser Permanente Southern California, and its contractors or cooperating agencies to refuse to reveal identifying information concerning research subjects if any of the following conditions exist:
 - (a) The subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of identifying information.
 - (b) Authorized personnel of the United States Department of Health and Human Services request such information for audit or program evaluation of the research project, or for investigation of Kaiser Permanente Southern California, and its contractors or cooperating agencies in carrying out the research project.
 - (c) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) or regulations promulgated there under (Title 21, Code of Federal Regulations).
- (2) This certificate requires that there be no disclosures of identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects, except as provided for in paragraph (1) above.
- (3) The confidentiality certificate does not govern the voluntary disclosure of identifying characteristics of research subjects.
- (4) This certificate does not represent an endorsement of the research project by the Department of Health and Human Services.
- (5) All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection.

- (6) This certificate is effective upon issuance, and will expire at the end of October 2011, or sooner if the holder is notified of cancellation in accordance with the procedures set out in 42 C.F.R. § 2a.8. The protection afforded by this certificate of confidentiality is permanent (including after death) for persons who participated as subjects in the research during any time the certificate was in effect.

Date: 10/18/06



James W. Stephens, Ph.D.

Acting Associate Director for Science, CDC



CONFIDENTIALITY CERTIFICATE

issued to

Employees of

University of Colorado Health Sciences Center

and Other Participants

conducting research known as

SEARCH FOR DIABETES IN YOUTH, PHASE 2 (SEARCH Phase 2)
Cooperative Agreement No. 5-U01-DP-000247-02

In accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)) this certificate is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research.

Under authority vested in the Secretary of Health and Human Services under that section, all persons who –

- (1) are employed by University of Colorado Health Sciences Center, and its contractors and cooperating agencies; and
- (2) have, in the course of that employment, access to the information which would identify individuals who are the subjects of a research project entitled “SEARCH for Diabetes in Youth, Phase 2”

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research, with the exceptions and limitations set forth below.

The purpose of SEARCH Phase 2 is to build on SEARCH Phase 1 which assessed the burden of diabetes with the onset in childhood and adolescence in the U.S. SEARCH Phase 2 will enhance the understanding of the natural history, complications, and risk factors of diabetes mellitus with the onset in childhood and adolescence.

As provided in section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)),

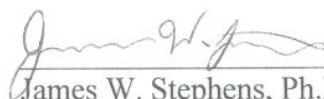
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

The following conditions apply to the protection provided under this certificate:

- (1) This certificate does not authorize University of Colorado Health Sciences Center, and its contractors or cooperating agencies to refuse to reveal identifying information concerning research subjects if any of the following conditions exist:
 - (a) The subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of identifying information.
 - (b) Authorized personnel of the United States Department of Health and Human Services request such information for audit or program evaluation of the research project, or for investigation of University of Colorado Health Sciences Center, and its contractors or cooperating agencies in carrying out the research project.
 - (c) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) or regulations promulgated there under (Title 21, Code of Federal Regulations).
- (2) This certificate requires that there be no disclosures of identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects, except as provided for in paragraph (1) above.
- (3) The confidentiality certificate does not govern the voluntary disclosure of identifying characteristics of research subjects.
- (4) This certificate does not represent an endorsement of the research project by the Department of Health and Human Services.
- (5) All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection.

- (6) This certificate is effective upon issuance, and will expire at the end of October 2011, or sooner if the holder is notified of cancellation in accordance with the procedures set out in 42 C.F.R. § 2a.8. The protection afforded by this certificate of confidentiality is permanent (including after death) for persons who participated as subjects in the research during any time the certificate was in effect.

Date: 10/18/06



James W. Stephens, Ph.D.

Acting Associate Director for Science, CDC



CONFIDENTIALITY CERTIFICATE

issued to

Employees of

University of South Carolina

and Other Participants

conducting research known as

SEARCH FOR DIABETES IN YOUTH, PHASE 2 (SEARCH Phase 2)
Cooperative Agreement No. 5-U01-DP-000254-02

In accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)) this certificate is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research.

Under authority vested in the Secretary of Health and Human Services under that section, all persons who –

- (1) are employed by the University of South Carolina, and its contractors and cooperating agencies; and
- (2) have, in the course of that employment, access to the information which would identify individuals who are the subjects of a research project entitled "SEARCH for Diabetes in Youth, Phase 2"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research, with the exceptions and limitations set forth below.

The purpose of SEARCH Phase 2 is to build on SEARCH Phase 1 which assessed the burden of diabetes with onset in childhood and adolescence in the U.S. SEARCH Phase 2 will enhance the understanding of the natural history, complications, and risk factors of diabetes mellitus with onset in childhood and adolescence.

As provided in section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)),

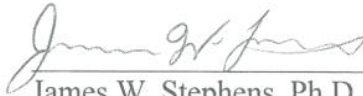
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

The following conditions apply to the protection provided under this certificate:

- (1) This certificate does not authorize the University of South Carolina, and its contractors or cooperating agencies to refuse to reveal identifying information concerning research subjects if any of the following conditions exist:
 - (a) The subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of identifying information.
 - (b) Authorized personnel of the United States Department of Health and Human Services request such information for audit or program evaluation of the research project, or for investigation of the University of South Carolina, and its contractors or cooperating agencies in carrying out the research project.
 - (c) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) or regulations promulgated there under (Title 21, Code of Federal Regulations).
- (2) This certificate requires that there be no disclosures of identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects, except as provided for in paragraph (1) above.
- (3) The confidentiality certificate does not govern the voluntary disclosure of identifying characteristics of research subjects.
- (4) This certificate does not represent an endorsement of the research project by the Department of Health and Human Services.
- (5) All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection.

- (6) This certificate is effective upon issuance, and will expire at the end of October 2011, or sooner if the holder is notified of cancellation in accordance with the procedures set out in 42 C.F.R. § 2a.8. The protection afforded by this certificate of confidentiality is permanent (including after death) for persons who participated as subjects in the research during any time the certificate was in effect.

Date: 10/18/06



James W. Stephens, Ph.D.
Acting Associate Director for Science, CDC