APPLICATION TO CONDUCT RESEARCH INVOLVING TENNCARE MEMBER PROTECTED HEALTH INFORMATION

PROJECT SUMMARY

Date of Application: _____

Proposed Start Date of Project: _____

Target Completion Date of Project: _____

Project title: _____

Project Duration: _____

Brief Project Summary: _____

_____

I. ORGANIZATION INFORMATION

A. Applicant Organization (Legal Name): _____

Project Director: _____

Street Address or P.O. Box: _____

City, State, Zip Code: _____

Telephone: _____ Email: _____

B. Other persons who should be contacted if more information is needed:

1. Name: _____

Title: _____

Address (if different from above): _____

Telephone: _____ Email: _____

2. Name: _____

Title: _____

Address (if different from above): _____

Telephone: _____ Email: _____

C. Name and address of sponsor(s) or funding organization(s) for this project:

_____

_____

_____

D. OTHER ORGANIZATIONS PARTICIPATING IN THIS STUDY OR PROJECT. Name(s) of organization(s) and/or individual(s) who will obtain the protected health information (PHI) of any TennCare member and describe their roles in this study (include organization, address, and phone number):

A "Supplemental Assurances Form" must be completed by EACH organization (or individual) listed and must be signed by responsible officials of that organization. The completed forms must be submitted as an attachment(s) to this application form. *(See Attachment A)*

II. INSTITUTIONAL REVIEW BOARD

Has this research project been reviewed and approved by an Institutional Review Board? IRB approval is required if the study requires the receipt of TennCare member PHI.

If YES, provide the name of the board, date of approval and attach a copy to this application.

If NO, indicate reason:

III. STUDY PROTOCOL OR PROJECT ACTIVITIES

You may attach a copy of your complete study protocol (or selected sections) to this application; however, the abstract that you provide in response to these questions should be self-contained so that it can serve as a complete and accurate description of the project separate from any appended document.

A. Describe the health or medical problem or question addressed by your study or activities.

B. List the primary study or project objectives, and include a description of the hypotheses to be tested.

C. Summarize the project's data collection methods, indicating specific follow-up procedures, if they apply.

D. Summarize the project's analysis, indicating how the data will be used.

E. Describe any data files that will be linked with the data provided and specify the source of these data files.

F. In what form and to whom will the results of your study or activities be released?

IV. RECORDS AND/OR IDENTIFIABLE DATA REQUIRED

A. Identify the records you will require to address the needs of this project.

B. Please list the data variables that you need:

C. List the data years you require for this project: e.g.; 2007 or 2002-2005, etc.;

D. In what form and to whom will the results of your study or activities be released

E. How many future requests do you expect to make?

V. CONFIDENTIALITY AND SECURITY OF IDENTIFIABLE DATA

A. How will you maintain the confidentiality and security of identifiable data obtained from the TennCare records?

B. Disposition of identifiable data: (NOTE: TennCare requires that paper records or electronic data files be destroyed at the end of the study, or as soon thereafter as possible. This includes all data files with or without personal identifiers.)
   a. How long will you store copies of records or other identifiable data? _____
   b. How will you dispose of copies of records or other identifiable data? _____

C. Approximate date of study completion: _____

D. Will you require follow-up investigations based on information provided by TennCare records to obtain additional information from decedent's next-of-kin, study subjects, physicians, hospitals, and/or other individuals or facilities mentioned in the records?

☐ YES ☐ NO

If YES, briefly describe the following:

1. Types of follow-up respondents to be contacted. (If the answer to this question includes families, next-of-kin, or the study subject, please answer the following questions 2 and 3.)

2. Information to be obtained from respondents. (A copy of the survey form or questionnaire must also be attached and labeled appropriately).

3. Methods to be used in conducting such investigations. (A copy of consent form and initial contact letter to be mailed to follow-up individual must also be attached and labeled appropriately.)

_____

_____

_____

E. Will any of the identifiable data obtained from the records and/or follow-up investigations be used as a basis for legal, administrative, or other actions which may directly affect particular individuals as a result of their specific identification in this project?

☐ YES ☐ NO

If YES, please explain.

_____

F. Will the identifiable data obtained from the records or follow-up investigations be used either directly or indirectly for any project or purpose other than the one described in Part III?

☐ YES ☐ NO

If YES, briefly describe the other research project(s) or purpose(s) for which the data will be used. A separate application form must be submitted for each project which will be using protected data obtained from TennCare records.

_____

VI. APPLICANT ASSURANCES

The undersigned hereby agrees to the following terms and conditions related to this application and to the use of information obtained from TennCare.

The identifiable data obtained following written approval from TennCare shall be used only for the proposed study and the purposes described in the "Summary of Study Protocol or Project Activities" (Part III).

Use of the information for a project or purpose other than that described in Parts III and IV shall not be undertaken unless a separate application form for the subsequent project has been submitted to and approved by TennCare.

No individually identifiable data shall be released without prior written approval by TennCare.

Paper records and electronic data files containing TennCare member data shall be destroyed upon completion of the study or as soon as possible thereafter.

If data extracted from TennCare records are used in any publication, the following statement must be included in such publication or any other release of the data:

These data were supplied by the State of Tennessee, Department of Finance and Administration, Division of TennCare, Nashville, TN. TennCare specifically disclaims responsibility for any analyses, interpretations or conclusions.

A copy of any published materials or study results shall be made available to TennCare upon request.

I have thoroughly reviewed the contents of the TennCare policy on Use of Enrollee Records in Research, available on the TennCare website, and I shall adhere to the applicable guidelines set forth therein.
All statements entered in this application are true, complete, and correct to the best of my knowledge and belief.

_____

Project Director's Name (Print)

_____

Project Director's Title

_____

Organization

_____

Signature Date

ATTACHMENT A

TENNCARE APPLICATION FOR RESEARCH DATA

SUPPLEMENTAL ASSURANCES FORM

Each additional organization listed on the Research application form as participating in this study must complete and sign this separate Supplemental Assurances Form. The Research applicant must submit the Supplemental Assurances Form(s) as an attachment to the Research applicant's application form.

Name: _____

Title: _____

Organization: _____

Street Address or P.O. Box: _____

City, State, Zip Code: _____

Telephone: _____ Email: _____

A. How will you maintain the confidentiality and security of identifiable data obtained from TennCare records?

_____

B. Disposition of identifiable data:

1. How long will you store copies of records or other identifiable data? _____
2. How will you dispose of copies of records or other identifiable data? _____

C. Approximate date of study completion: _____

D. Will you require follow-up investigations to obtain additional information from decedent's next- of-kin, study subjects, physicians, hospitals, and/or other individuals or facilities mentioned on the records?

☐ YES ☐ NO

If YES, briefly describe the following:

1. Types of follow-up respondents to be contacted. (If the answer to this question includes families, next-of-kin, or the study subject, please answer the following questions 2 and 3.)

   _____

   _____

   _____

2. Information to be obtained from respondents. (A copy of the survey form or questionnaire must also be attached and labeled appropriately.)

   _____

   _____

   _____

3. Methods to be used in conducting such investigations. (A copy of consent form and initial contact letter to be mailed to follow-up individual must also be attached and labeled appropriately.)

_____

_____

_____

E. Will any of the identifiable data obtained from the records and/or follow-up investigations be used as a basis for legal, administrative, or other actions which may directly affect particular individuals as a result of their specific identification in this project?

☐ YES ☐ NO

If YES, please explain.

_____

F. Will the identifiable data obtained from the records or follow-up investigations be used either directly or indirectly for any project or purpose other than the one described in Part III of the Application for Access to Protected Data?

☐ YES ☐ NO

If YES, briefly describe the other research project(s) or purpose(s) for which the data will be used. A separate application form must be submitted for each project which will be using protected data obtained from TennCare.

_____

_____

APPLICANT ASSURANCES

The undersigned hereby agrees to the following terms and conditions related to this application and to the use of information obtained from TennCare.

The identifiable data obtained following written approval from TennCare shall be used only for the proposed study and the purposes described in the "Summary of Study Protocol or Project Activities" (Part III).

Use of the information for a project or purpose other than that described in Parts III and IV shall not be undertaken unless a separate application form for the subsequent project has been submitted to and approved by TennCare.

No individually identifiable data shall be released without prior written approval by TennCare.

Paper records and electronic data files containing TennCare member data shall be destroyed upon completion of the study or as soon as possible thereafter.

If data extracted from TennCare records are used in any publication, the following statement must be included in such publication or any other release of the data:

These data were supplied by the State of Tennessee, Department of Finance and Administration, Division of TennCare, Nashville, TN. TennCare specifically disclaims responsibility for any analyses, interpretations or conclusions.

A copy of any published materials or study results shall be made available to the Tennessee TennCare upon request.

All the statements entered in this application are true, complete, and correct to the best of my knowledge and belief.

_____

Project Director's Name (Print)

_____

Project Director's Title

_____

Organization

_____

Signature Date