

Send completed application to: Kimberly Cozzens, MA
Cardiac Initiatives Research Manager
Cardiac Services Program
1 University Place, Suite 218
Rensselaer, NY 12144
ksc06@health.state.ny.us

FOR DOH USE

Request Number:

1. Applicants

a. Project Director/Principal Investigator: *(Individual primarily responsible for designing and conducting the research project)*

Name _____
Organization _____
Title _____
Address _____

Telephone _____ Email _____

b. Contact Person: *(Individual who may be contacted regarding this application)*

Name _____
Organization _____
Title _____
Address _____

Telephone _____ Email _____

c. Organizational Representative: *(Individual authorized to enter agreements and attest to organizational support for this research project)*

Name _____
Organization _____
Title _____
Address _____

Telephone _____ Email _____

2. Summary of Proposed Research Project

a. Title of Research Project:

Title _____

Note: The summary provided below should be a thorough and accurate description of the research project. All of the items below must be addressed in this summary. Omissions or vagueness will not be interpreted in your favor.

b. Research Question: *Briefly state your specific research question(s) and study hypotheses.*

c. Research Aims and Objectives: *Provide a discussion of the main issues to be addressed and the analyses to be conducted.
Demonstrate the scientific merit of this research project including answers to the following questions:*

- Does this research project address an important problem? What is the relationship between the proposed research and the etiology, prevention, diagnosis, or treatment of cardiac diseases or conditions? If the aims of the research project are achieved, how will scientific knowledge or clinical practice and treatment of cardiac diseases or conditions be advanced? What will be the effect of this research project on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field?

d. Benefits: *As required by PHL 2816-a, describe how the research project contributes to one or more of the following:*

- the quality of care and outcomes experienced by patients receiving cardiac services;
- the appropriateness of cardiac services;
- access to cardiac services; and/or
- the cost effectiveness of cardiac services.

f. Methods: Describe in detail the methods you propose using to answer the research question(s) described above. Be as specific as possible regarding variables that will be used and statistical techniques employed.

g. Publication/Dissemination: Please indicate intended products to be created using the Cardiac Data Set (e.g. articles, book chapter, poster, abstract, presentation, etc). Note: Materials acceptable for publication may not include direct findings, listings, or information derived from the Cardiac Data Set if such findings, listings, or information can, by themselves or in combination with other data, be used to directly or indirectly identify any particular individual or establishment described therein.

3. Project Participants

a. Publication/Dissemination: Identify below all project participants. Project participants include all individuals who will have access to the Cardiac Data Set in any form as well as study partners, contractors, consultants, collaborators, assistants, associates, etc. Please note that anyone who is the author of a publication resulting from this study is also regarded as a project participant.

For every individual listed, there must be a complete affidavit attached. In the event that this research project is approved, any changes to the list of project participants must be made in writing to the Cardiac Services Program. No individual may be granted access to the Cardiac Data Set without completing an affidavit and obtaining approval of NYSDOH.

ONLY THOSE INDIVIDUALS LISTED BELOW WHO HAVE AN ATTACHED, SIGNED AFFIDAVIT MAY HAVE ANY ACCESS TO THE CARDIAC DATA SET PROVIDED PURSUANT TO THIS APPLICATION.

Name	Title	Organization	Role in Research	Prior Cardiac Services Information user? (Y/N)

b. Experience and Qualifications of the Project Participants: *Please describe the qualifications, credentials and previous research experience of all project participants. In particular, address the experience of the Project Director / Investigator in: designing and/or overseeing similar research projects, using large datasets, and using data containing sensitive personal health information. Additionally, specifically identify which individual(s) will be responsible for manipulation of the Cardiac Data Set and execution of analysis, including a description of similar previous experience:*

c. Contractors: *Identify any contractors involved and their role.*

4. Confidentiality of Cardiac Data Set

a. Narrative: *Describe how the confidentiality of the requested Cardiac Data Set will be maintained. Include an explanation of how and where the Cardiac Data Set will be stored, as well as how and when the Cardiac Data Set will be disposed of after the study/project is completed. Also describe the safeguards that currently exist for maintaining the confidentiality of other sensitive data that may be in use by the project director.*

b. Securing and Storing Cardiac Services Information:

Will the cardiac services information be stored at a location other than the organization's physical site?

No

Yes

If yes, explain the reason for off-site storage, identify the storage site and vendor or contractor responsible for off-site storage and describe the security standards in place at the off-site storage location.

5. Fees, Sponsors, and Institutional Support

a. Fees: *Based on information provided in item 2.e.1 above, calculate your total project fee.*

1. Number of CSRS data sets (by discharge year)	1.
2. Number of PCIRS data sets (by discharge year)	2.
3. Total number of data sets (Line 1 + Line 2)	3.
4. Cost per data set:	4. \$2,500.00
5. Total cost for requested data (Line 3 × Line 4)	5.

b. Describe how your institution supports your efforts in this research project.

c. Sources of Funding: *Specify all sources of funding/sponsors for this research project.*

6. Protection of Human Subjects

Has there been a consideration of whether submission to an IRB is needed?

No *If no, explain why there has been no such consideration:*

Yes *If yes, attach a summary of the project description materials submitted to the IRB and a copy of the IRB determination for this project.*

7. Required Signatures

Project Director

- I have read and understand the data use agreement and anticipate entering into that agreement without modification should the research project be approved. I also understand that an organizational representative will also be required to enter into the data use agreement.*
- I understand that the New York State Department of Health may request additional information as part of this application and may impose additional conditions and contingencies on the release and use of the requested Cardiac Data Set.*
- I understand that the New York State Department of Health maintains the right, while the information is in my possession, to request my submission of periodic statements describing how the requested Cardiac Data Set has been used.*
- I understand that the Commissioner, as part of his/her conditions for the release of Cardiac Data Sets, may specifically require the requestor to send the New York State Department of Health copies of reports or publications based on cardiac services information from this request.*
- I attest that this Cardiac Data Set will be used for the sole purpose of this research study/project. The Cardiac Data Set will not be shared with any person or entity not covered by this request. I must notify the Department of any or all changes to the team or to the research project.*
- I attest that, if approved, this project will be conducted in compliance with all state and federal laws, policies and regulations governing the privacy and security of data and protection of human subjects.*

Signature of Project Director _____

Print or Type Name and Title _____

Affiliation _____

Organization

Signature of Organization Representative _____ Date _____

Print or Type Name and Title _____

Affiliation _____

FOR DOH USE
Request Number:

STATE OF:

COUNTY OF:

_____ (RESEARCHER), being duly sworn, deposes and says:

1. I am identified in the attached Cardiac Data Set Request as an individual who will use or have access to a Cardiac Data Set consisting of Cardiac Services Information as defined in NYS Public Health Law Section 2816-a and requested for the purpose of the research project _____ (INSERT PROJECT TITLE).
2. The Cardiac Data Set I may receive is confidential and is subject to strict limitations on disclosure, see NYS Public Health Law Section 2816-a. I have been informed by the New York State Department of Health and am aware that no attempt may be made by me to identify specific individuals whose Cardiac Services Information has been received, except where specific authorization has been given by the Commissioner of the New York State Department of Health (Commissioner) pursuant to NYS Public Health Law Section 2816-a.
3. I also acknowledge that I have been informed by the New York State Department of Health and am aware of the following restrictions on use of any Cardiac Data Set to which the Commissioner grants access and agree to the following:
 - a. Access to any Cardiac Data Set will be granted only to the individual(s) who have signed affidavits on file with the New York State Department of Health;
 - b. The Cardiac Data Set will be used only for the purposes stated in the Summary of Proposed Research Project;
 - c. No Cardiac Data Set or portion thereof will be released or disclosed to any person or entity, or published in any manner whatsoever without prior written approval pursuant to Public Health Law Section 2816-a.;
 - d. The Cardiac Data Set will be kept in a secure environment and only authorized users will have access;
 - e. The Researcher is required to destroy all Cardiac Data Sets and derivatives containing Cardiac Services Information within two years. The limit is defined as two years from when the Cardiac Data Set is provided to the researcher by the Cardiac Services Program. A written request to extend this time period may be submitted to Cardiac Services Program for approval;
 - f. The Cardiac Services Program may perform an on-site audit of the use and security of the Cardiac Data Set received and I will cooperate if requested in the event of such an audit;
 - g. Any publication or report produced by this organization and/or using the Cardiac Data Set will acknowledge the source of the Cardiac Data Set as the New York State Department of Health
4. I am aware that any unauthorized disclosure of the Cardiac Data Set or any portion thereof received pursuant to Public Health Law Section 2816-a may result in the violators being subject to penalties and prosecution under New York Public Health Law §§12, 12-b and 2816-a as well as other applicable laws.

_____ DATE

_____ SIGNATURE

_____ RESEARCHER NAME

_____ TITLE

_____ ORGANIZATION

Subscribed and sworn to before me on

This _____ day of _____, _____

_____ NOTARIZATION

As project director for this application, I have approved the access and usage of the cardiac services information for this research initiative for the requesting individual above.

_____ PROJECT DIRECTOR SIGNATURE

_____ NAME (PRINTED)

FOR DOH USE

Request Number:

STATE OF:

COUNTY OF:

_____, (PRINT NAME), being duly sworn, deposes and says:

1. I am _____ (INSERT TITLE) and am authorized to sign on behalf of _____ (ORGANIZATION). My signature indicates organizational support for this request and my responsibility for maintaining the confidentiality of the Cardiac Data Set released pursuant to this application for the purpose of the research project _____ (INSERT PROJECT TITLE).
2. The Cardiac Data Set that this Organization may receive is confidential and is subject to strict limitations on disclosure, see Public Health Law Section 2816-a. I have been informed by the New York State Department of Health and am aware that no attempt may be made by this Organization or anyone employed by or under contract with this Organization to identify specific individuals whose cardiac services information has been received, except where specific written authorization has been given by the Commissioner of the New York State Department of Health (Commissioner) pursuant to Public Health Law Section 2816-a.
3. I also acknowledge that I have been informed by the New York State Department of Health and am aware of the following restrictions on use of any Cardiac Data Set to which the Commissioner grants access and agree to the following:
 - a. Access to any Cardiac Data Set will be granted only to the individual(s) who have signed affidavits on file with the New York State Department of Health;
 - b. The Cardiac Data Set will be used only for the purposes stated in the Summary of Proposed Research Project;
 - c. No Cardiac Data Set or portion thereof will be released or disclosed to any person or entity, or published in any manner whatsoever without prior written approval pursuant to Public Health Law Section 2816-a.
 - d. The Cardiac Data Set will be kept in a secure environment and only authorized users will have access;
 - e. The Organization is required to destroy all Cardiac Data Sets and derivatives containing Cardiac Services Information within two years. The limit is defined as two years from when the Cardiac Data Set is provided to the researcher by the Cardiac Services Program. A written request to extend this time period may be submitted to Cardiac Services Program for approval;
 - f. The Cardiac Services Program may perform an on-site audit of the use and security of the Cardiac Data Set received and I will cooperate if requested in the event of such an audit;
 - g. Any publication or report produced by this organization and/or using the Cardiac Data Set will acknowledge the source of the Cardiac Data Set as the New York State Department of Health.
4. I am aware that any unauthorized disclosure of the Cardiac Data Set or any portion thereof received pursuant to Public Health Law Section 2816-a may result in the violators being subject to penalties and prosecution under New York Public Health Law §§12, 12-b and 2816-a as well as other applicable laws.

DATE

SIGNATURE OF ORGANIZATION REPRESENTATIVE

NAME

TITLE

ORGANIZATION

Subscribed and sworn to before me on

This _____ day of _____, _____

NOTARIZATION