

August 8, 2018

Dear Requestor:

Enclosed please find a copy of the New York State Department of Health (NYSDOH), Office of Quality and Patient Safety (OQPS), Sepsis Clinical Data Project Data Use Agreement (SCD DUA). The data are collected by NYSDOH through a contract with a third-party pursuant to 10 New York Codes, Rules and Regulations (NYCRR) §405.4.

Prior to completing the SCD DUA, please contact OQPS at [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov). This initial contact email should indicate that your organization is planning to submit a SCD DUA. OQPS will schedule a conference call with the Project Lead to obtain information about the project and assign a DOH Sponsor if the project concept is approved. The SCD DUA should not be completed until after a DOH Sponsor is assigned.

The purpose of the SCD DUA is to form an agreement between the Project Lead and NYSDOH as to the terms and conditions under which the release of Sepsis Clinical Data (SCD) will be made. The SCD DUA must be completed and submitted along with data security attestation (Attachment A), Individual DUAs for each project participant (Attachment B), list of requested data elements (Attachment D), and a proposed analysis plan (Attachment E). Completed applications should be sent via email to: [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov).

Upon receipt of the required documentation, OQPS will review the proposed project documentation and determine if the project will be approved using the criteria set forth in this document. Upon approval of the project, OQPS personnel will create and transmit the appropriate data set to the Data Custodian identified in the SCD DUA through a secure mechanism.

All results related to this project which are derived from analyses that used the SCD provided by OQPS must be reviewed by OQPS prior to publication or public release. OQPS requires at least 45 business days to review proposed releases of the results and respond to the Requestor. The provided SCD must be destroyed within 30 days of the SCD DUA end date and the destruction attestation (Attachment C) submitted to OQPS.

**Please note that a separate SCD DUA and Individual DUAs are required for each project.**

Sincerely,

The OQPS Sepsis Team

**Table of Contents**

CHECKLIST (To be completed before submitting the DUA) .....3

Section 1: Requestors..... 4

Section 2: Summary of Proposed Research Project..... 5

Section 3: Release of Project Results ..... 7

Section 4: Sepsis Clinical Data Requested ..... 8

Section 5: Storage and Disposal of Data..... 9

Section 6: Project Participants ..... 10

Section 7: Protection of Human Subjects ..... 14

Section 8: Institutional Support..... 14

Section 9: Modifications ..... 15

Section 10: Required Signature (Project Lead) ..... 16

Attachment A: NYSDOH Data Security Requirements

Attachment B: Individual Data Use Agreement – NYS Sepsis Initiative

Attachment C: Data Disposal Attestation Form – Affidavit

Attachment D: List of Sepsis Clinical Data Elements

Attachment E: Proposed Analysis Plan

Attachment F: Sepsis Clinical Data Project Process Diagram

Attachment G: Data Security General Terms and Conditions

**DUA Checklist**

- Have you carefully read all DUA Sections 1-10?
- Have you provided responses to all DUA Sections 1-10?
- Have you attached additional project participants information (Section 6)?
- Have you attached a copy of the IRB submission materials and a copy of the IRB determination for this project (Section 7)?

***Attachments to the Project Data Use Agreement***

All Attachments to the DUA are considered to be a part of the DUA, though these may not apply to all Requestors.

- Have you read and signed **Attachment A:** NYSDOH Data Security Requirements - Attestation?
- Have all project participants read and signed **Attachment B:** Individual Data Use Agreement NYS Sepsis Initiative?
- Have you read **Attachment C:** Data Disposal Attestation Form Affidavit?
- Have you provided **Attachment D:** List of Sepsis Clinical Data Elements?
- Have you provided **Attachment E:** Proposed Analysis Plan?
- Have you carefully read **Attachment F:** Sepsis Clinical Data Project Process Diagram?
- Have you read **Attachment G:** Data Security General Terms and Conditions?

The Sepsis Clinical Data Project Data Use Agreement (SCD DUA) is used to request access to the Sepsis Clinical Data (SCD) collected by the Office of Quality and Patient Safety (OQPS), New York State Department of Health (NYSDOH) through a designated subcontractor pursuant to 10 New York Codes, Rules and Regulations (NYCRR) §405.4. The SCD DUA must be completed and submitted along with signed NYSDOH Data Security Requirements - Attestation (Attachment A), Individual DUAs for each project participant (Attachment B), Data Disposal Attestation (Attachment C), list of requested SCD elements (Attachment D), and proposed analysis plan (Attachment E). Upon receipt of all required documentation, OQPS will review the SCD DUA and associated documentation to determine if the project is approved. Upon approval of the project, OQPS will create and transmit the appropriate data set to the Data Custodian via a secure data portal.

**Please note that separate SCD DUAs and Individual DUAs are required for each project that your organization wishes to undertake using the SCD.**

***For DOH Administrative Use Only***

***Request Number:*** \_\_\_\_\_

*Date Received:* \_\_\_\_\_

*Date Reviewed:* \_\_\_\_\_

*Date Approved:* \_\_\_\_\_

*Reviewed by (print name/signature):* \_\_\_\_\_

*Approved by (print name/signature):* \_\_\_\_\_

**Section 1(a): Requestors – Project Lead**

**NOTE:** Prior to submitting the data use agreement, the Requestor must have a conference call with DOH sepsis personnel. **You will be assigned a DOH Sponsor after this call takes place.** Please see the process flow document for additional guidance (**Attachment F**).

**Note that the Project Lead is the person who legally represents the project participants entering into the terms of this SCD DUA.**

<b>Project Lead Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Street Address:</b>	
<b>City, State, Zip:</b>	
<b>Telephone:</b>	
<b>Business Email Address:</b>	
<b>DOH Sponsor:</b>	
<b>Describe your role in this project:</b>	
<b>Describe your organization's experience and capacity to handle this project:</b>	
<b>Describe your experience and qualifications to lead this project:</b> This should include a summary of your education; experience (name(s) of organization(s), timeframe(s), relevant responsibilities); total years of experience related to this project.	

**Section 1(b): Requestors – Data Custodian**

Please provide the requested information for the Data Custodian. **The discharge-level SCD will only be released to the Data Custodian, who is responsible for securing the data.**

The Data Custodian may share the data with designated analyst(s), but the discharge-level data must not be shared with any other individual project participants. Aggregate data summaries may be shared with the project participants identified on this form. The Data Custodian is legally responsible for destroying the data upon project completion, and for completing the Data Disposal Attestation Form (see **Attachment C**).

<b>Data Custodian Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Street Address:</b>	
<b>City, State, Zip:</b>	
<b>Telephone:</b>	
<b>Business Email Address:</b>	
<p><b>Please list your qualifications to serve as Data Custodian for this project:</b> This should include a summary of your education; experience (name(s) of organization(s), timeframe(s), relevant responsibilities); total years of experience related to this project.</p>	

**Section 2: Summary of Proposed Project**

<b>Project Title:</b>	
<b>What type of project is this?</b>	<input type="checkbox"/> Quality Improvement <input type="checkbox"/> Research <input type="checkbox"/> Other (please specify)

<p><b>Please briefly state the goals of this project. What is (are) the aim(s) of the project?</b> Please provide the proposed analysis plan as an <b>Attachment E</b> to this document. The analysis plan should include a list of proposed analyses/data summaries that will be prepared using the SCD along with a detailed description of the proposed methodology used for each analysis. For research projects, please include at a minimum research question(s) and proposed hypothesis(es).</p>	<p>Is the analysis plan attached?</p> <p><input type="checkbox"/> Yes <span style="float: right;"><input type="checkbox"/> No</span></p> <p><u>Project Goals:</u></p>
<p><b>What are the benefits of this research project?</b> Is the project intended to advance the scientific knowledge for severe sepsis or septic shock?</p>	<p><input type="checkbox"/> Yes (if yes, please describe below) <span style="float: right;"><input type="checkbox"/> No</span></p>
<p>Is the project intended to advance clinical care or contribute to the body of literature related to the appropriateness of interventions used to treat patients who are diagnosed with severe sepsis or septic shock?</p>	<p><input type="checkbox"/> Yes (if yes, please describe below) <span style="float: right;"><input type="checkbox"/> No</span></p>
<p>Is the project intended to contribute to improving the quality of care and outcomes experienced by patients diagnosed with severe sepsis or septic shock in New York State?</p>	<p><input type="checkbox"/> Yes (if yes, please describe below) <span style="float: right;"><input type="checkbox"/> No</span></p>
<p>Is the project intended to investigate access to treatments for patients diagnosed with severe sepsis or septic shock or address health disparities for this population?</p>	<p><input type="checkbox"/> Yes (if yes, please describe below) <span style="float: right;"><input type="checkbox"/> No</span></p>
<p>Is the project intended to investigate the cost of severe sepsis or septic shock in New York State?</p>	<p><input type="checkbox"/> Yes (if yes, please describe below) <span style="float: right;"><input type="checkbox"/> No</span></p>

<p>If you answered “No” to all of the above questions, please describe the intended benefits of the project.</p>	
<p><b>What negative consequences may result from the proposed analysis? How will you address these potential negative consequences if they occur?</b></p>	
<p><b>What are the deliverables for this project? Please name the targeted journal/publication if a deliverable is a manuscript to be published in a peer-reviewed journal.</b></p>	
<p><b>What is the timeline for this project?</b></p>	<p>Target Start Date:</p> <p>End Date:</p>

**Section 3: Release of Project Results**

Please note that all results related to this project which are derived from analyses that used the SCD provided to you by OQPS must be reviewed by the NYSDOH prior to publication or public release. Publications include not only manuscripts but also abstracts, presentations, posters, reports, or documents that take any other form intended for release to a broader audience beyond the individuals listed in this report.

No results may be released that can, by themselves or in combination with other data, be used to directly or indirectly identify any individual or facility. If your project does not have a NYSDOH Sponsor who is also a co-author, any publication must note that the conclusions in the publication are not those of the NYSDOH unless the NYSDOH explicitly agrees to the conclusions upon review of the publication.

**Please Note: NYSDOH OQPS requires at least 45 business days to review proposed releases of the results and respond to the Requestor.**

<p><b>Please initial and date here to indicate that you understand and agree to abide by the 45-day review policy listed above:</b></p>	<p>Initial:</p> <p>Date:</p>
---	------------------------------

**Section 4: Sepsis Clinical Data Requested**

This DUA grants the Requestor access to certain data from the Sepsis Clinical Database System collected pursuant to 10 NYCRR §405.4.

Only the minimum amount of demographic and clinical information determined necessary to conduct the proposed research project will be released. No direct patient identifiers such as names or social security numbers (see 45 CFR § 164.514(b)(2)) are available for request. While no admission date/time, discharge date/time or intervention date/times will be released, derived variables such as time to intervention or length of stay are available for request.

SCD contains severe sepsis/septic shock discharges from the NYS Article 28 licensed hospitals starting from calendar year 2015 forward. All reported SCD events associated with the requested range of dates will be provided pending project approval.

**For the detailed specifications of the SCD data elements and year-specific availability, please refer to the online data dictionaries available at <https://ny.sepsis.ipro.org/>.**

**Please note: Starting from January 2017, hospitals that have annual volume of sepsis/septic shock cases exceeding 400, were eligible to report a sample of cases with a minimum requirement of submission 400 cases per year. These cases were selected by NYSDOH through application of a multi-stage sampling technique.**

<p><b>Data Elements:</b> A list of available data elements is included in this DUA (see <b>Attachment D</b>). Please include an attachment indicating which data elements are requested, the date range for each element, and why the data element is important to your research project.</p>	<p>Is the requested data elements list attached?</p> <p><input type="checkbox"/> Yes <span style="margin-left: 200px;"><input type="checkbox"/> No</span></p>
<p><b>Linkages:</b> Any linkage of SCD to other data sets must be approved by OQPS.</p>	<p>Are you planning to link the SCD to another data set?</p> <p><input type="checkbox"/> Yes (please list the data set(s) below) <span style="margin-left: 20px;"><input type="checkbox"/> No</span></p>
<p>If you are planning to link the SCD to another data set, please describe why this data linkage is necessary for your project.</p>	
<p>Will linking the SCD to the other data source(s) potentially enhance any of the data sources (including SCD) to the point of becoming identifiable?</p>	<p><input type="checkbox"/> Yes (if yes, please describe below) <span style="margin-left: 20px;"><input type="checkbox"/> No</span></p>

<p><b>Please indicate the level of data access that is requested for this project.</b> <b>Check all that apply:</b></p>	<p><input type="checkbox"/> Limited Discharge Level Data (contains patient indirect identifiers according to HIPAA standards)</p> <p><input type="checkbox"/> Aggregate Data Summaries</p>
---	--

**Section 5: Storage and Disposal of Data**

Storage:  
Sepsis Clinical Data must be stored in a secure location/manner (see **Attachment A** and **Attachment G**). Please note that NYSDOH requires that all entities handling individual patient data maintain a record of data use. NYSDOH reserves the right to audit these data use records to ensure compliance with this DUA. (See **Attachment A**, NYSDOH Data Security Requirements – Attestation).

Disposal:  
The data must be destroyed upon completion of the project. This destruction must occur within 30 days of the end date set forth in Section 2 of this DUA, unless you have requested in writing and been granted an extension to the end date by OQPS. If you received an extension, then SCD must be destroyed within 30 days of the revised end date.

You must submit an affidavit specifying the date of destruction and the method of destruction used. (See **Attachment C**, Data Disposal Attestation Form – Affidavit). The SCD and/or the storage medium containing the SCD must be destroyed in accordance with applicable ITS destruction policies (ITS Policy S13-003 Sanitization/Secure Disposal and S14-003 Information Security Controls or successor).

<p><b>Please initial and date here to indicate that the data will be protected per NYSDOH Data Security Requirements as outlined in Attachment A:</b></p>	<p>Initial:</p> <p>Date:</p>
---	------------------------------

<p><b>Please describe how the data will be stored and confidentiality maintained:</b></p>	
---	--

<p><b>Please indicate the method of data destruction that you will apply upon project completion:</b></p> <p><b>NOTE:</b> File deletion is not an acceptable means of data destruction.</p>	<input type="checkbox"/> Shredding the Hard Drive <input type="checkbox"/> Overwrite the Data (using a Department of Defense-approved method) <input type="checkbox"/> Physically destroy the Hard Drive on Which the Data are Stored <input type="checkbox"/> Demagnetize (Degauss) the Hard Drive <input type="checkbox"/> Other (please specify)
<p><b>Please initial and date here to indicate that you have read, understand, and agree to the NYSDOH data destruction policy as outlined above:</b></p>	<p>Initial:</p> <p>Date:</p>

**Section 6: Project Participants**

Please identify all additional project participants below. Project participants include all individuals who will have access to the Sepsis Clinical Data in any form (including aggregate data summaries). Project participants include study partners, contractors, consultants, collaborators, assistants, associates, and anyone who is an author of a publication (manuscript, poster, presentation, report, etc.) resulting from this project.

**A completed Individual DUA form (Attachment B) must be submitted for every project participant. Any change to the project participants list must be made in writing to OQPS (submit to [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov)). Only those individuals listed below who have an attached, signed Individual DUA may have any level of access to the SCD pursuant to this SCD DUA.**

Please attach additional sheets if necessary.

Additional Project Participant #1	
<b>Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Street Address:</b>	
<b>City, State Zip:</b>	
<b>Telephone:</b>	
<b>Email Address:</b>	
<b>Role in Project:</b>	<input type="checkbox"/> Data Analyst <input type="checkbox"/> Manuscript Editor <input type="checkbox"/> Significant Contributor (Help Develop Analysis Plan, Interpret Results, Write Publication, etc.)

<b>Data access level:</b>	<input type="checkbox"/> Discharge Level (Analyst and Custodian Only) <input type="checkbox"/> Aggregate Summaries <input type="checkbox"/> No Access Needed
<b>Please describe the experience and qualifications the Participant contributes to this project:</b> This should include a summary of education; experience (name(s) of organization(s), timeframe(s), relevant responsibilities); total years of experience related to this project.	
<b>Individual DUA attached?</b>	<input type="checkbox"/> Yes <span style="float: right;"><input type="checkbox"/> No</span>

<b>Additional Project Participant #2</b>	
<b>Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Street Address:</b>	
<b>City, State Zip:</b>	
<b>Telephone:</b>	
<b>Email Address:</b>	
<b>Role in Project:</b>	<input type="checkbox"/> Data Analyst <input type="checkbox"/> Manuscript Editor <input type="checkbox"/> Significant Contributor (Help Develop Analysis Plan, Interpret Results, Write Publication, etc.)
<b>Data access level:</b>	<input type="checkbox"/> Discharge Level (Analyst and Custodian Only) <input type="checkbox"/> Aggregate Summaries <input type="checkbox"/> No Access Needed
<b>Please describe the experience and qualifications the Participant contributes to this project:</b> This should include a summary of education; experience (name(s) of organization(s), timeframe(s), relevant responsibilities); total years of experience related to this project.	
<b>Individual DUA attached?</b>	<input type="checkbox"/> Yes <span style="float: right;"><input type="checkbox"/> No</span>

<b>Additional Project Participant #3</b>	
<b>Name:</b>	

<b>Title:</b>	
<b>Organization:</b>	
<b>Street Address:</b>	
<b>City, State Zip:</b>	
<b>Telephone:</b>	
<b>Email Address:</b>	
<b>Role in Project:</b>	<input type="checkbox"/> Data Analyst  <input type="checkbox"/> Manuscript Editor  <input type="checkbox"/> Significant Contributor (Help Develop Analysis Plan, Interpret Results, Write Publication, etc.)
<b>Data access level:</b>	<input type="checkbox"/> Discharge Level (Analyst and Custodian Only)  <input type="checkbox"/> Aggregate Summaries  <input type="checkbox"/> No Access Needed
<b>Please describe the experience and qualifications the Participant contributes to this project:</b> This should include a summary of education; experience (name(s) of organization(s), timeframe(s), relevant responsibilities); total years of experience related to this project.	
<b>Individual DUA attached?</b>	<input type="checkbox"/> Yes <span style="margin-left: 200px;"><input type="checkbox"/> No</span>

<b>Additional Project Participant #4</b>	
<b>Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Street Address:</b>	
<b>City, State Zip:</b>	
<b>Telephone:</b>	
<b>Email Address:</b>	
<b>Role in Project:</b>	<input type="checkbox"/> Data Analyst  <input type="checkbox"/> Manuscript Editor  <input type="checkbox"/> Significant Contributor (Help Develop Analysis Plan, Interpret Results, Write Publication, etc.)
<b>Data access level:</b>	<input type="checkbox"/> Discharge Level (Analyst and Custodian Only)  <input type="checkbox"/> Aggregate Summaries  <input type="checkbox"/> No Access Needed

<p><b>Please describe the experience and qualifications the Participant contributes to this project:</b> This should include a summary of education; experience (name(s) of organization(s), timeframe(s), relevant responsibilities); total years of experience related to this project.</p>	
<p><b>Individual DUA attached?</b></p>	<p><input type="checkbox"/> Yes <span style="float: right;"><input type="checkbox"/> No</span></p>

<b>Additional Project Participant #5</b>	
<p><b>Name:</b></p>	
<p><b>Title:</b></p>	
<p><b>Organization:</b></p>	
<p><b>Street Address:</b></p>	
<p><b>City, State Zip:</b></p>	
<p><b>Telephone:</b></p>	
<p><b>Email Address:</b></p>	
<p><b>Role in Project:</b></p>	<p><input type="checkbox"/> Data Analyst</p> <p><input type="checkbox"/> Manuscript Editor</p> <p><input type="checkbox"/> Significant Contributor (Help Develop Analysis Plan, Interpret Results, Write Publication, etc.)</p>
<p><b>Data access level:</b></p>	<p><input type="checkbox"/> Discharge Level (Analyst and Custodian Only)</p> <p><input type="checkbox"/> Aggregate Summaries</p> <p><input type="checkbox"/> No Access Needed</p>
<p><b>Please describe the experience and qualifications the Participant contributes to this project:</b> This should include a summary of education; experience (name(s) of organization(s), timeframe(s), relevant responsibilities); total years of experience related to this project.</p>	
<p><b>Individual DUA attached?</b></p>	<p><input type="checkbox"/> Yes <span style="float: right;"><input type="checkbox"/> No</span></p>

<b>Additional Project Participant #6</b>	
<p><b>Name:</b></p>	
<p><b>Title:</b></p>	
<p><b>Organization:</b></p>	
<p><b>Street Address:</b></p>	
<p><b>City, State Zip:</b></p>	
<p><b>Telephone:</b></p>	

<b>Email Address:</b>	
<b>Role in Project:</b>	<input type="checkbox"/> Data Analyst <input type="checkbox"/> Manuscript Editor <input type="checkbox"/> Significant Contributor (Help Develop Analysis Plan, Interpret Results, Write Publication, etc.)
<b>Data access level:</b>	<input type="checkbox"/> Discharge Level (Analyst and Custodian Only) <input type="checkbox"/> Aggregate Summaries <input type="checkbox"/> No Access Needed
<b>Please describe the experience and qualifications the Participant contributes to this project:</b> This should include a summary of education; experience (name(s) of organization(s), timeframe(s), relevant responsibilities); total years of experience related to this project.	
<b>Individual DUA attached?</b>	<input type="checkbox"/> Yes <span style="float: right;"><input type="checkbox"/> No</span>

<b>Section 7: Protection of Human Subjects</b>	
<b>Is submission to your organization's Institutional Review Board (IRB) required?</b>	<input type="checkbox"/> No (if no, please explain why) <input type="checkbox"/> Yes (please attach a summary of the materials submitted to the IRB and a copy of the IRB determination for this project)

<b>Section 8: Organizational Support</b>	
<b>Please describe how your organization supports your efforts in this project:</b>	
<b>Please identify all sources of funding/sponsors for this project:</b>	

**Section 9: Modifications**

Projects are approved for the exact specifications as listed in this SCD DUA. All project modifications (including the project goals, changes to the analysis plan, changes to project participants, etc.) must be submitted in writing to [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov) and approved by OQPS. Requests for new data linkages require a new project DUA and do not qualify for modifications to the existing SCD DUA.

**Please initial and date here to indicate that you understand and agree to the Project Modifications policy listed above:**

Initial:

Date:

**Section 10: Required Signature (Organizational Representative)**

The Organizational Representative must be capable of legally binding the organization to the terms of this Agreement.

- I have read and understand the SCD DUA and anticipate entering into the agreement without modification should the project be approved.
- I agree to establish appropriate administrative, technical, and physical safeguards (e.g. locked file cabinets, password protected computer files, limitation of staff access on a need-to-know basis, etc.) to maintain the security and protect the confidentiality of the SCD as outlined in Attachment A and to prevent unauthorized use or access to it.
- I attest that the SCD set will only be shared with individuals who are listed as project participants and who have a signed Individual DUA on file with OQPS. Furthermore, the discharge level data will not be shared/viewed by any project participant other than the Data Custodian and/or Data Analyst who share aggregate summaries with the other project participants.
- I agree to provide OQPS (via [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov)) with copies of all documents (manuscripts, posters, presentations, tables, charts, studies, reports, etc.) produced using or referencing the SCD released under this SCD DUA not less than 45 business days prior to submitting for publication. I understand that any publications using SCD must be approved by OQPS prior to publication.
- I attest that I have reviewed the SCD Elements (Attachment D) and will make all reasonable attempts to assure that any and all statements made about the SCD in any documents are accurate.
- I understand that OQPS may request additional information as part of this data request and may impose additional conditions and contingencies on the release and use of the requested SCD.
- I understand that OQPS maintains the right, while the SCD is in the Data Custodian's possession, to request the submission of periodic statements describing how the SCD set has been used. In addition, OQPS may conduct audits on the use and security of the data received, and I agree to participate in such audits and to provide periodic reports as requested by OQPS.
- I understand that the SCD may be used for the sole purpose of the project described in this document and any changes to the project must be made in writing to [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov). I understand that additional projects require additional SCD DUAs and Individual DUAs, as applicable.
- I attest that this project will be conducted in compliance with all New York State and federal laws, policies and regulations governing the privacy and security of data and protection of human subjects.
- I attest that the SCD will be stored in a secure environment as outlined in Attachment A and only the Data Custodian and/or Data Analyst will have access.
- I agree to notify OQPS of any and all changes to Project Participants, their titles and/or affiliations in writing. No individual or entity shall be permitted access to the SCD in any form until they answer to OQPS's satisfaction all elements of the Project Participants' section of the SCD DUA. I understand that it is the Project Lead's responsibility to keep OQPS informed of changes to the Project Participants once

notified.

- I agree that in the event of any data breach, I will notify OQPS within 24 hours through an email to [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov).
- I attest that the SCD will be destroyed at the end of the approved project in accordance with Attachment C.
- I agree to notify OQPS within seven (7) business days if the research project is completed before the aforementioned retention date and to destroy the data within 30 business days of such notice. I also agree to send written certification of the destruction of the files to OQPS, and acknowledge that the date of destruction is not contingent upon action by OOPS.
- I understand that NYSDOH retains all ownership rights to the SCD provided under this agreement and that neither I nor my organization obtain any right, title, or interest in any of the SCD furnished by OQPS.
- I understand that, although NYSDOH retains all ownership rights to the SCD, the organization shall bear the cost and liability for any breaches of the SCD entrusted to them. Furthermore, if OQPS determines that the risk of harm requires notification of affected individual persons of the security breach and/or other remedies, the organization agrees to carry out these remedies without cost to NYSDOH.
- I understand that in the event OQPS determines or has a reasonable belief that reuse or disclosure that is not authorized by this agreement has occurred or may have occurred OQPS at its sole discretion may require the Project Lead to:
  - a) promptly investigate and report to OQPS the Project Participant determinations regarding any alleged or actual unauthorized use, reuse or disclosure;
  - b) promptly resolve any problems identified by the investigation;
  - c) if requested by OQPS, submit a formal response to an allegation of unauthorized use, reuse or disclosure;
  - d) if requested by OQPS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and
  - e) if requested by OQPS, destroy the SCD it received from OQPS under this DUA
- I understand that as a result of OQPS's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, OQPS may refuse to release further SCD to the Project Lead, Project Participants, and/or other individuals from the organization for a period of time to be determined by OQPS, which may include permanent loss of access to the data.
- I understand that this agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon notice, OQPS will cease release of SCD and will notify the Project Participant to destroy the files. Those provisions regarding protection of the confidentiality of the SCD and responsibilities, should there be a breach, survive the termination of the agreement.
- I attest that the representations and statements made in this agreement and submitted to NYSDOH are complete and accurate.

<b>Organizational Representative – Signature</b>	
<b>Print Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Date:</b>	
<b><i>Notary Public Section</i></b>	
<b>Subscribed and sworn to before me on this day of:</b>	
<b>Notary Public Signature and Stamp:</b>	

---

**Attachment A: NYSDOH Data Security Requirements – Attestation**

The following data protection standards must be in place at the organization receiving the Sepsis Clinical Data (SCD). By initialing first line in Section 5 of the SCD DUA and submitting this form, the project is agreeing to the following requirements:

1. I agree that SCD are required to be stored on a network server that uses Transport Layer Security 1.1 or later, or another federally recognized encryption protocol to protect data in transit from unauthorized access. The server must be located behind a properly activated firewall, and data must remain encrypted at rest using federally approved advanced encryption standard (AES) encryption.
2. I agree that, if a network server is unavailable, a stand-alone PC may be used to store the sepsis clinical data. If a stand-alone system is used, it will have an encrypted hard drive, have no access to or from the Internet, exist in a secure location (such as a locked office), be accessible only to the Data Custodian and/or Data Analyst, be password protected, and have an enabled screensaver set to activate at 5 minutes of inactivity.
3. I agree that the storage system will be able to generate a log of unique IDs that access the data, from what location, and the dates and times. This audit log will be presented to the New York State Department of Health (NYSDOH), Office of Quality and Patient Safety (OQPS), within 5 business days, upon request.
4. I agree that all remote connections from offsite locations shall be approved by OQPS. Approved remote connections will occur over a Virtual Private Network (VPN) and comply with the NYS Encryption Standard (NYS-S14-007), a document describing New York's encryption standards for data in transit.
5. I agree that, if using a local workstation to access the data, it will be connected to the network from a secure location, be accessible only to authorized individuals, use password protection, and have an enabled screensaver set to activate at no more than 5 minutes of inactivity.
6. I agree that data shall not be stored on removable media (i.e., CDs, thumb drives, or other external storage devices), unless approved by OQPS. If approved, the device will be encrypted using a Federal Information Processing Standard (FIPs) approved algorithm.
7. I agree that geocoding will not be done in the cloud or with online software programs. All methods and applications used for geocoding will be approved by the OQPS.
8. I agree that access to approved SCD will be permitted to the Data Custodian identified in the SCD DUA only upon approval of the Data Custodian's signed Individual DUA. The user will then be authorized to use the data only and solely for the purpose(s) stated in the SCD DUA.
9. I agree that the SCD will not be shared with anyone, in any form, unless described to and approved by OQPS. Doing so would cause a breach of security and subject NYSDOH to possible penalties.
10. I agree I will notify OQPS within 24 hours of any data breach through an email to [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov).
11. I agree that, at the end of the project, all SCD must be destroyed using a non-recoverable destruction method. Documentation of the destruction process is required.

---

**Attachment A: NYSDOH Data Security Requirements – Attestation (Continued)**

By signing this agreement, the Project Lead and Data Custodian agree to abide by all provisions set forth in this agreement and any attachments or appendices.

<b><i>Project Lead Section</i></b>	
<b>Project Lead – Signature</b>	
<b>Print Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Date:</b>	

<b><i>Data Custodian Section</i></b>	
<b>Data Custodian – Signature</b>	
<b>Print Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Date:</b>	

---

### Attachment B - Individual Data Use Agreement

This agreement is by and between the New York State Department of Health (NYSDOH), Office of Quality and Patient Safety (OQPS) and an applicant for Sepsis Clinical Data (SCD) from OQPS, hereinafter termed "Project Participant". The NYSDOH agrees to provide the approved Project Participant with a SCD set that resides in the Sepsis Clinical Data System managed by a third-party contractor and collected under Title 10 New York Codes, Rules and Regulations (NYCRR) §405.4. In exchange, the Project Participant agrees to the following:

- (1) to restrict the use of the SCD, and not permit others to use the SCD for any purpose other than those specified and approved by OQPS through the SCD DUA to which this Individual DUA is attached;
- (2) to make no use of knowledge about the identity of a person inadvertently discovered by the review of the SCD, to safeguard or destroy the information, and to inform the Data Custodian regarding any potential breach or unauthorized disclosure as soon as possible following the discovery of such potential breach or disclosure;
- (3) not to disclose, use, reuse, sell, rent, lease, loan, or otherwise grant access to the SCD or any portion thereof covered by this DUA except as OQPS shall authorize in writing;
- (4) not to disclose direct findings, listings, or information derived from the SCD 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;
- (5) not to attempt to link records included in the SCD to any other individually identifiable source of information. This includes attempts to link the data to other SCD sets received for the Project Participant's other projects or those received by other project participants unless explicitly approved by OQPS as part of the SCD DUA;
- (6) to review the SCD Elements (Attachment D) and to make all reasonable attempts to assure that any and all statements made about the SCD in any documents are accurate;
- (7) to provide OQPS (via [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov)) with copies of all documents (manuscript, poster, presentation, table, chart, study, report, etc.) produced using or referencing the SCD released under this SCD DUA not less than 45 business days prior to submitting for publication;
- (8) to include in any and all documents a disclaimer which states that the views presented are those of the authors and do not necessarily represent those of NYSDOH or OQPS unless the NYSDOH explicitly agrees to the conclusions upon review of the publication;
- (9) to report, within 24 hours, any loss of SCD or disclosure of SCD to any unauthorized person to the Data Custodian who must report the breach to OQPS within 24 hours of notification via email to [sepsis.clinical.data@health.ny.gov](mailto:sepsis.clinical.data@health.ny.gov).

By signing this agreement, the Project Participant agrees to abide by all provisions set forth herein this agreement.

<b><i>Project Participant Section</i></b>	
<b>Project Participant – Signature</b>	
<b>Print Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Date:</b>	

<b><i>Project Lead Section</i></b>	
<b>Project Lead – Signature</b>	
<b>Print Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Date:</b>	

**Page Intentionally Left Blank**

**Attachment C: Data Disposal Attestation Form – Affidavit**

**Project Participant Section**

Once the project period specified by the Requestor has expired, the Data Custodian must attest that all SCD has been destroyed and specify the date and method of destruction.

The SCD and/or the storage medium containing the SCD must be destroyed in accordance with applicable ITS destruction policies (ITS Policy S13-003 Sanitization/Secure Disposal and S14-003 Information Security Controls or successor).

<b>Data Custodian Signature:</b>	
<b>Print Name:</b>	
<b>Title:</b>	
<b>Organization:</b>	
<b>Street Address:</b>	
<b>City, State, Zip:</b>	

I understand that the New York State Department of Health (NYSDOH) specifically prohibits the use of the Sepsis Clinical Data (SCD) for any purpose, other than the purpose of which was stated in the approved SCD Project Data Use Agreement (DUA), without the prior written approval of the Office of Quality and Patient Safety (OQPS), NYSDOH. As the project associated with the SCD DUA has been completed, I understand that the SCD may no longer be used for any purpose whatsoever and must be destroyed within 30 days of the SCD DUA end date.

I have retained none of the SCD disclosed to be under the above-referenced DUA and I understand that any SCD that I might recall from memory remains confidential.

**Please check one of the following responses regarding how you destroyed the data:**

<input type="checkbox"/> <b>Shredded the Hard Drive</b>	Indicate the location at which the hard drive was shredded:  Date:
<input type="checkbox"/> <b>Overwrote the Data (using a Department of Defense approved method)</b>	Indicate the method/software used to overwrite the data:  Date:
<input type="checkbox"/> <b>Physically Destroy the Hard Drive on Which the Data are Stored</b>	Indicate the method used to destroy the hard drive:  Date:
<input type="checkbox"/> <b>Demagnetize (Degauss) the Hard Drive</b>	Indicate the method used to destroy the hard drive:  Date:

---

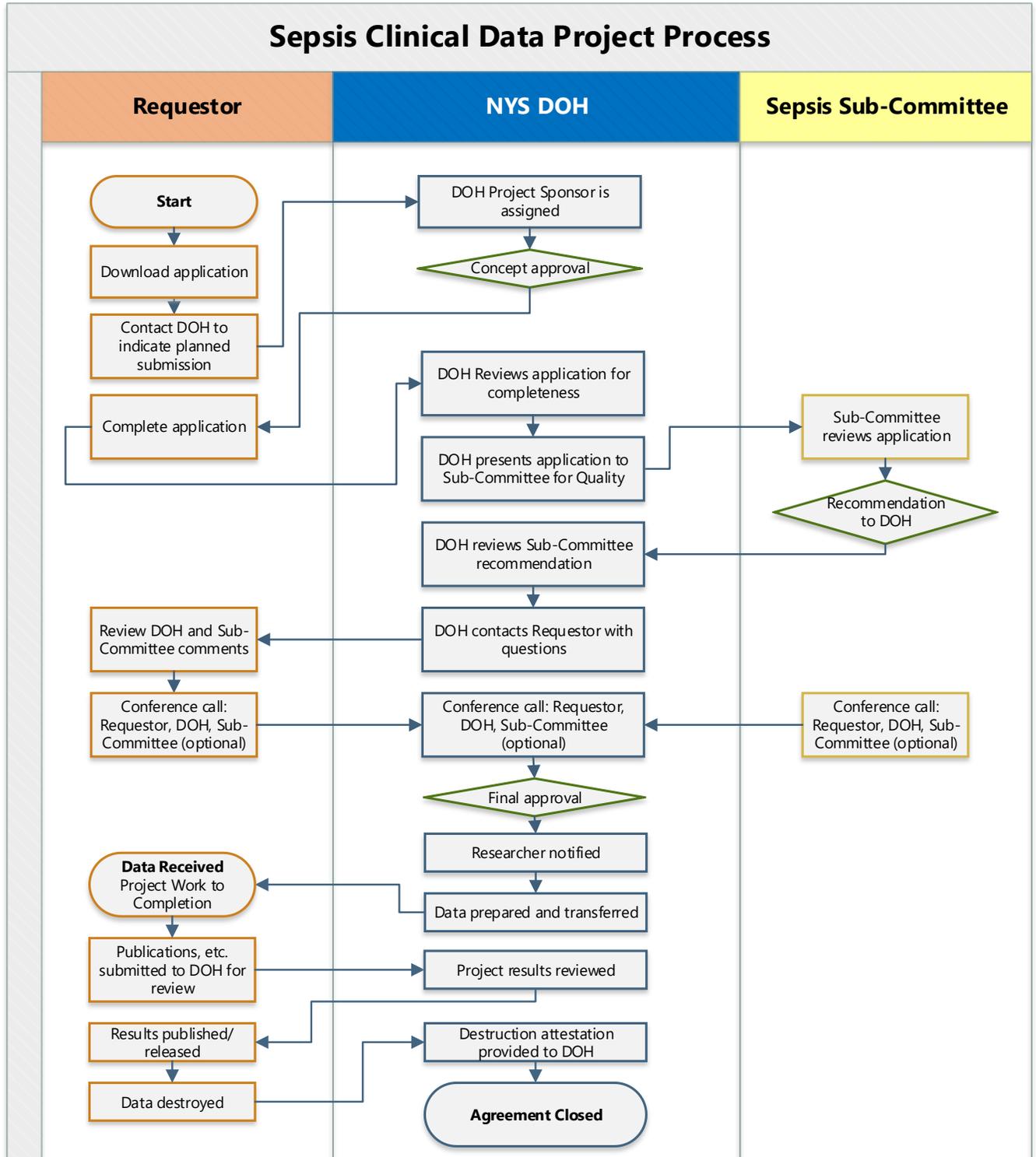
<b><i>Notary Public Section</i></b>	
<b>Subscribed and sworn to before me on this day of:</b>	
<b>Notary Public Signature and Stamp:</b>	

### **Attachment E: Proposed Analysis Plan**

Please include and attach a proposed analysis plan for this project, including a list of proposed analyses/data summaries that will be prepared using the SCD. Please be as specific as possible regarding your research methodology and attach as many sheets as needed. For research projects, please include (at a minimum) all research question(s) and proposed hypothesis(es). Requestors should also be prepared to answer any questions regarding the proposed analysis plan prior to project approval.

Attachments for the proposed analysis plan should include the heading “Attachment E – Proposed Analysis Plan.”

Attachment F: Sepsis Clinical Data Project Process Diagram



## Attachment G: Data Security General Terms and Conditions

### A. General Requirements

The Requestor agrees that it shall house and maintain Sepsis Clinical Data (SCD) in a manner consistent with the following requirements:

1. Host all SCD and maintain and implement procedures to physically and logically segregate SCD from the Requestor's other data.
2. Establish and maintain appropriate environmental, safety and facility procedures, data security procedures and other safeguards against the destruction, corruption, loss or alteration of the hosting services and SCD, and to prevent unauthorized access, alteration or interference by third parties of the same.
3. Utilize industry best practices and technology (including appropriate firewall protection, intrusion prevention tools, and intrusion detection tools) to protect, safeguard, and secure SCD against unauthorized access, use, and disclosure. The Requestor shall constantly monitor for any attempted unauthorized access to, or use or disclosure of SCD, and shall immediately take all necessary and appropriate action in the event any such attempt is discovered, promptly notifying the Office of Quality and Patient Safety of any material or significant breach of security with respect to any such materials.
4. When software vulnerabilities are revealed and addressed by a vendor patch, the Requestor will obtain the patch from the applicable vendor and categorize the urgency of application as either "critical" or "non-critical" in nature. The determination of the critical versus non-critical nature of patches is solely at the reasonable discretion of the Requestor in consultation with ITS standards. The Requestor will apply all critical security patches, hot fixes, or service packs as they are tested and determined safe for installation.

### B. Data Location and Related Restrictions

1. All SCD shall remain in the United States. Any SCD stored, or acted upon, must be located solely in Data Centers within the United States. Services which directly or indirectly access SCD may only be performed from locations within the United States. All helpdesk, online, and support services which access any SCD must be performed from within the United States.
2. All remote connections will occur over a Virtual Private Network (VPN) and comply with the NYS Encryption Standard ([NYS-S14-007](#)).

### C. Portable Devices

1. The Requestor shall not place SCD on any portable device unless such device is located and remains within Requestor's Data Center and such use has been approved by the Department.

**Attachment G: Data Security General Terms and Conditions (continued)**

**D. Data Ownership**

1. The New York State Department of Health (NYSDOH) shall own all right, title and interest in any SCD received by the Requestor.

**E. NYSDOH Access to Data**

1. The NYSDOH shall have access to SCD at all times, through the term of this agreement. The NYSDOH shall have the ability to import or export SCD in piecemeal or in its entirety at the NYSDOH discretion.