

|  |  |
| --- | --- |
| MHCC Data Request Number |  |
| Application Received |  |
| Application Approved |  |
| Data Obtained |  |

**INSTRUCTIONS**

TRACKING TABLE (For MHCC Use Only)

Application for D.C. Inpatient Discharge Data

This form is required for Applicants requesting access to the D.C. Inpatient Discharge Limited Access Database. **Only current and prospective applicants for a Certificate of Need (CON) or exemption from CON review and interested parties to CON reviews (and their consultants and attorneys) are eligible to receive this data.** Applicants must also complete all the attachments. The completed Application and the Data Management Plan will be used by MHCC to determine whether the request meets the criteria for data release, pursuant to MHCC’s Data Use Agreement with the D.C. Hospital Association and COMAR [10.25.05](http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.25.05.%2A) Incomplete applications will be returned to the Applicant, and the request will be delayed.

#### Where to submit documents:

* Completed application packages should be scanned and emailed to: mhcc.datarelease@maryland.gov
* A hard copy Application is acceptable and should be sent, with the application fee, to:

Maryland Health Care Commission 4160 Patterson Avenue,

Baltimore, MD 21215, ATTN: MHCC Data Release

* Enclose a cover note page that includes the project title, requesting organization’s name, and applicant’s name.
* If an invoice is needed, send a request to: mhcc.datarelease@maryland.gov

#### Note to Applicants:

* All application attachments will be incorporated in the Approved Data Use Agreement (DUA)

**Questions?** Email mhcc.datarelease@maryland.gov

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| --- |
| **PROJECT INFORMATION** |
| **Project Title** |
|  |
| **Scheduled Project Start Date** |  | **Scheduled Project End Date** |  |
| **MHCC Staff Approved Pre-Application Number** |  |
| **Project Overview:** *Provide an abstract or brief summary (150 words) of the specific purpose and objectives of the Project.* |
|  |

|  |
| --- |
| **Applicant** *(principal investigator, project manager, individual responsible for the research team using the data)* |
| Name |  |
| Title |  |
| E-Mail Address |  |
| Telephone Number |  |
| Organization Name |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |

|  |
| --- |
| **Requesting Organization** *(Agency)* |
| Organization Name |  |
| Website |  |
| E-Mail Address |  |
| Telephone Number |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |

|  |
| --- |
| **Data Custodian** *(person responsible for receiving, organizing, storing, and archiving data)* |
| Name |  |
| Title |  |
| E-Mail Address |  |
| Telephone Number |  |
| Organization/Company *(if different from Requesting Organization)* |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |
| Relationship to Requesting Organization *(e.g., Contractor)* |  |

|  |
| --- |
| **Project Contact** *(person responsible for all communications with MHCC)* |
| Name |  |
| Title |  |
| E-Mail Address |  |
| Telephone Number |  |
| Organization Name |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |

# ATTACHMENT A: SCOPE OF WORK

#### Project Purpose

Describe how the data will be used to support an application for a Certificate of Need (CON), request for exemption from CON review, or interested party comments. Specify whether you have already submitted a letter of intent, CON application, request for exemption, or interested party comments and provide the matter/docket number if available. **If you have not yet submitted a CON application, letter of intent, request for exemption, or interested party comments, please complete Attachment H: Prospective CON Applicant Affidavit.**

####

#### Project Methodology

* 1. Provide a written description of the project methodology, state the project objectives, the protocol, software and/or identify relevant study questions and analysis method to allow MHCC to understand how the D.C. Inpatient Discharge Data will be used to meet project objectives or address research questions.

#### Publication and Dissemination

You may only publish the results of your analysis in furtherance of a CON application, exemption request, or interested party comments.

* 1. All public displays of D.C. Inpatient Discharge Data, regardless of the medium, must comply with MHCC’s cell size suppression policy, as set forth in the Data Use Agreement. Describe how you will ensure that any public display will suppress every cell containing less than 11 observations and suppress percentages or other mathematical formulas that result in the display of every cell with less than 11 observations.
	2. Identify the lowest geographical level of analysis of data you will present for publication or presentation (e.g., state level, city/town level, zip code level, etc.). Will maps be presented? What methods will be used to ensure that individuals cannot be identified?

#  ATTACHMENT B: REQUESTED DATA ELEMENTS

**Please attach a detailed data specification for your request, including requested variables/fields, filters, and justification for RIF fields, if appropriate. Justify why the data requested are the minimum data required.** Please reference the [Data Elements Dictionary](http://mhcc.maryland.gov/mhcc/pages/apcd/apcd_datamanuals/documents/DC_Inpatient_Variable_List.xls) to identify requested fields.

#  ATTACHMENT C: LINKAGE

### Linkages

### Data linkage involves combining D.C. Inpatient Discharge data with other data to create a more extensive database for analysis.

### Do you intend to merge or link D.C. Inpatient Discharge Data with other data?

### ☐ Yes ☐ No If **Yes:**

### What are the files to be linked?

### Why is this linkage needed?

### Which D.C. Inpatient Discharge data elements will be linked to the data elements in the external file?

### What methodology or algorithm will be used to create this match? If you intend to create a unique algorithm, describe how it will link each dataset.

* 1. What variables from each of the source files will be included in the final linked analytic file?

### Explain why the linkages are needed.

### Describe the specific steps the Organization will take to prevent the identification of individuals in the linked files.

# ATTACHMENT D: DATA MANAGEMENT PLAN

#### Certification

The undersigned certifies and agrees as follows:

* The data will be used only for approved purposes of analysis and presentation.
* The Organization will comply with all administrative, technical, and procedural policies and physical safeguards established to protect the confidentiality of the data and to prevent unauthorized access to the data.
* The data will be encrypted at rest and in motion on storage media (backup tapes, local hard drives, network storage, et al.) with at least an AES-256 standard or stronger.
* The Organization understands and agrees that any intentional breach of confidentiality will result in termination of the Data Use Agreement.
* Anti-virus software or service is active on any server or endpoint containing the D.C. Inpatient Discharge data.
* Staff with access to PHI or other sensitive data have received all relevant training The Organization has policies and procedures in place to address:
* The sharing, transmission, and distribution of PHI
* The physical possession and storage of PHI
* The destruction of PHI upon completion of data use
* Confidentiality agreements with each individuals, including contractors, who will access PHI
* Agreements governing the use and disclosure of PHI with all non-employees who will access PHI

## Confirm you certify and agree to the above statement

#### Responsible Individuals

* 1. Provide the name(s) of the custodian responsible for receiving, organizing, storing, or archiving data.

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| E-Mail Address |  |
| Telephone Number |  |
| Organization Name |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |

* 1. Provide the name of the person who will notify MHCC of any breach of the D.C. Inpatient Discharge data, Data Use Agreement, or the Data Management Plan

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| E-Mail Address |  |
| Telephone Number |  |
| Organization Name |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |

* 1. Provide the name of the person responsible for ensuring proper data destruction upon the termination of the Data Use Agreement, and submission of the Certification of Data Destruction.

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| E-Mail Address |  |
| Telephone Number |  |

|  |  |
| --- | --- |
| Organization Name |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |

* 1. Provide the name of the person who will notify MHCC of any project staffing changes, maintain the roster of staff who have formal, documented permission to access specific files for specific purposes, and ensure that all individuals with access to the data comply with the Data Use Agreement.

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| E-Mail Address |  |
| Telephone Number |  |
| Organization Name |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |

#### Physical Possession and Storage of Data Files

1. Where will the data be stored?
	* Cloud
	* Physical location(s)
	* Both
2. Provide the delivery address for the data, including the location where the data will be stored.

i.

Delivery Add

|  |  |
| --- | --- |
| Address |  |
| City/Town |  |
| State |  | Zip Code |  |

ii. Storage Address

|  |  |
| --- | --- |
| Address |  |
| City/Town |  |
| State |  | Zip Code |  |

1. Provide the name and address of the Cloud Service Provider

|  |  |
| --- | --- |
| Address |  |
| City/Town |  |
| State |  | Zip Code |  |

1. Describe the name and data security assessment level of each physical location and the Cloud Service Provider where the data will be stored. Provide evidence that the proposed computing environment meets or exceeds NIST 800-53v4 security standards. Identify all certifications held by entities that will store or hold data.
2. SOC 2 Type Audit
3. HITRUST Certification
4. ISO 27001 Audit Certification
5. Independent external HIPAA standards Assessment
6. SSAE 16 Overview, and/or
7. FedRAMP Certification
8. Has each individual who will access the data agreed to the Request Organization’s privacy and security rules when using D.C. Inpatient Discharge data files? ☐ Yes ☐ No
9. Within the last 12 months, has each individual who will access D.C. Inpatient Discharge data received training on the proper handling of protected health information and/or personal data? ☐ Yes ☐ No. If no provide a brief description of the circumstances and detail the training that each such person will receive and by what date.
10. Explain the infrastructure (facilities, hardware, software, etc.) that will secure the D.C. Inpatient Discharge data files.
11. Briefly describe the policies and procedures regarding the physical possession and storage of D.C. Inpatient Discharge data files.
12. Briefly describe the system or the process to track the status and roles of the individuals with access to the D.C. Inpatient Discharge data files.
13. Briefly describe physical and technical safeguards that will be used to protect D.C. Inpatient Discharge data files.
14. Briefly describe how the data will be backed up and how the backup files will be managed.

#### Data Sharing, Electronic Transmission, and Distribution

1. Briefly describe the Requesting Organization’s policies and procedures regarding the sharing, transmission, and distribution of sensitive data files (including Data Sharing Agreements).
2. Describe the Requesting Organization’s policies and procedures applicable to the physical removal, transport, and transmission of D.C. Inpatient Discharge data files.
3. By checking the boxes next to the following statements, you are confirming that the following requirements will be met.
	* Access to the data will be restricted to authorized users by requiring computer log-on with unique user accounts and passwords.

#### For data stored on a network drive and not on your computer hard drive:

* + - Access will be restricted by limiting folder access to approved study staff only.
		- Any data included in the network backup will be encrypted.

#### For data stored on the local hard drive of a computer:

* + - When not in use, the computer will be locked in a physically secured office, drawer, cabinet, or other container to which access is restricted to authorized study personnel.
		- When not in use, data will be encrypted with a key length of at least 256 bits.
1. Describe the Requesting Organization’s technical safeguards preventing unauthorized access to D.C. Inpatient Discharge data files:

|  |
| --- |
| Password protocols: |
|  |
| Log-on/log-off protocols |
|  |
| Session time out protocols |
|  |
| Encryption for data in motion and data at rest |
|  |
| Antivirus and anti-malware products |
|  |

1. If applicable, describe the Requesting Organization’s physical safeguards preventing unauthorized access and check all security features listed below that are present in the room containing D.C. Inpatient Discharge data files:
	* Recorded video
	* Access log of all individuals entering the room
	* Secure server rack
	* Access control limiting access only to authorized individuals
2. If applicable, identify the data transmission method(s) you plan to use.
	* VPN
	* Secure FTP
	* Encrypted email delivery system
	* Other, specify and identify why this meets minimum data security requirements below:
3. Describe the Requesting Organization’s policies and procedures to terminate access to D.C. Inpatient Discharge data files when individual staff members of project teams (including additional collaborating organizations) terminate their participation on a project. (May include staff exit interviews and immediate access termination).

#### Completion of Research Tasks And Data Destruction

Applicant must agree that the D.C. Inpatient Discharge data, all copies and backups must be destroyed immediately after the period of time necessary to fulfill the requirements of the data request in accordance with the terms and conditions of the Data Use Agreement. All data destruction must follow and conform to [NIST Special Publications 800-88, Guidelines for Media](https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-88r1.pdf) [Sanitization.](https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-88r1.pdf)

1. Describe the Requesting Organization’s process to complete the Certificate of Data Destruction form and the Requesting Organization’s policies and procedures to destroy data files upon completion of the project.
2. If a copy of the data is needed to be maintained for a longer period, please provide the reason a longer time period is necessary.

#  ATTACHMENT E: USE OF CONTRACTORS AND/OR CONSULTANTS (External Entities)

Provide the following information for all consultants and contractors who will have access to the D.C. Inpatient Discharge data. The Requesting Organization must have a written agreement with the contractor/consultant to ensure the use of D.C. Inpatient Discharge data to the approved project(s) of this application as well as the privacy and security standards set forth in the Data Use Agreement. D.C. Inpatient Discharge data may not be shared with any third party without prior written consent from MHCC, or an amendment to this Application.

|  |  |
| --- | --- |
| **Entity** | * Contractor ☐ Subcontractor ☐ Consultant
 |
| Organization Name |  |
| Title |  |
| Website |  |
| Contact Person |  |
| E-Mail Address |  |
| Telephone Number |  |
| Mailing Address |  |
| City/Town |  | State |  | Zip Code |  |
| Term of Contract |  |

1. Describe the tasks and products assigned to this entity for this project.
2. Describe the qualifications of this entity to perform and complete the tasks.
3. Describe the Requesting Organization’s oversight and monitoring of the activities and actions of this entity for this project, including how you will ensure the privacy and security of the D.C. Inpatient Discharge data to which the consultant or contractor has access.
4. Will this entity have access to or store the D.C. Inpatient Discharge data at a location other than the data custodian location, off-site server, and/or database? ☐Yes ☐No.

If yes, a separate Data Management Plan **must** be completed by this contractor/consultant.

#### [INSERT A NEW SECTION FOR ADDITIONAL CONTRACTOR/CONSULTANT ENTITIES NEEDED]

Version 2019 -1.0 8.16.2019

# ATTACHMENT F: APPLICANT QUALIFICATIONS

* 1. Describe previous experience using claims data. This question should be answered by the primary investigator/project manager and should encompass the experience of the entire project team who will be using the data.
	2. Resumes/CVs: When submitting your application package, include résumés or curricula vitae of the principal investigator/project manager and any project team with relevant experience

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#  ATTACHMENT G: OBLIGATIONS AND ATTESTATION

ATTESTATION OF APPLICANT

I,  **,** Applicant, solemnly affirm under penalties of perjury that the information contained in the Application its attachments, and this Attestation, is true and correct to the best of my knowledge, information and belief and that the requested D.C. Inpatient Discharge data is the minimum necessary to accomplish the Project. I accept my obligation to comply with all requirements in this Application and attachments, including:

* + 1. Compliance with all data privacy and security obligations.
		2. Execution of a Data Use Agreement approved by MHCC-staff prior to receipt of the requested data.
		3. Responsibility for assuring that the data has been destroyed at the conclusion of the project in accordance with the terms and conditions of the Data Use Agreement.
		4. Responsibility for assuring that specified MHCC staff is notified within 30 days when any person who has access to the D.C. Inpatient Discharge data is removed from or added to the MHCC-approved Project.
		5. Responsibility for assuring that each required report is sent to the MHCC staff within the time period specified in the Data Use Agreement; and
		6. Continuing compliance with the Data Management Plan.

|  |  |
| --- | --- |
| Applicant’s signature: |  |
| **Printed Name:** |  |
| Title: |  |
| Requesting Organization: |  |
| Date: |  |

# ATTACHMENT H: PROSPECTIVE CON APPLICANT AFFIDAVIT

**Required only if no letter of intent, CON applicant, exemption request, or interested party comments have been filed at the time of this data request.**

ATTESTATION OF APPLICANT

I,  **,** Applicant, solemnly affirm under penalties of perjury that the following is true and correct to the best of my knowledge, information and belief:

1. The purpose of this request is for project planning related to a potential CON application, exemption request, or interested party comments;
2. The D.C. Discharge Inpatient data I receive pursuant to this request will not be used for any other purposes;
3. I will not disclose any findings related to the D.C. Discharge Data except in furtherance of a future CON application, request for exemption from CON review, or interested party comments.

|  |  |
| --- | --- |
| Applicant’s signature: |  |
| **Printed Name:** |  |
| Title: |  |
| Requesting Organization: |  |
| Date: |  |