**ACCESS TO DE-IDENTIFIED HEALTH INFORMATION FOR RESEARCH FORM**

**North Carolina Controlled Substances Reporting System**

The purpose of this form is for the researcher to request access to de-identified health information maintained in the North Carolina Controlled Substances Reporting System by DMH/DD/SAS for research purposes. This form is designed to prompt the appropriate documentation for such access, including information required for accounting of disclosures by DMH/DD/SAS. Incomplete forms, or forms submitted without the required accompanying documentation, will be returned to the requester without being approved.

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| **SECTION I GENERAL INFORMATION** |
| **IRB STUDY NUMBER** | **TITLE OF STUDY** |
|       |       |
| **NAME OF PRINCIPLE INVESTIGATOR** | **ORGANIZATION** |
|  |       |
| **MAILING ADDRESS CITY STATE ZIP CODE** |
|       |
| **TELEPHONE** | **MOBILE** | **FAX** |
| (     )    -     x       | (     )     -     | (     )     -     |
| **NAME OF SPONSOR** | **TELEPHONE** |
|       | (     )    -     x       |
| **MAILING ADDRESS CITY STATE ZIP CODE** |
|       |
| **STUDY START DATE** | **STUDY END DATE** |
|       |       |
| **GENERAL DESCRIPTION OF STUDY** *Include the study’s general description, goals, objectives, and aims. This field will expand as needed. If completing offline, a separate sheet labelled “General Description of Study” may be attached.* |
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| **SECTION II COMPLETELY DE-IDENTIFIED HEALTH INFORMATION** |
| **The Controlled Substances Reporting System Act, N.C.G.S. 90-113.74 Confidentiality**, subsection (d) states, “The Department may provide data to public or private entities for statistical, research, or educational purposes only after removing information that could be used to identify individual patients who received prescription medications from dispensers.”  |
| **A. Completely De-Identified Health Information** (See description in Section V and check the box below to confirm you are requesting completely De-Identified Data. |
| **[ ]**  | I am requesting access to or disclosures of completely de-identified health information, i.e., information that **does not** **contain any of the identifiers listed in Section V-A** **(De-Identified Health Information)** of this form with respect to an individual patient.. I have attached **a copy of the IRB approval letter for this research.** |

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| **Section III DATA REQUESTED FOR RESEARCH PURPOSES /  ADDITIONAL INFORMATION** |
| **A. Data Requested** (Please be specific) |
| **I am requesting the following de-identified health information/data for research purposes.** *Include each data element requested. Explain how the requested de-identified data will be used for the proposed study. This field will expand as needed. If completing offline, a separate sheet labelled “Data Requested” may be attached.*      |
| **Data Start Date**       | **Data End Date**       | **Desired Delivery Date**       |
| **B. Obligations** |
| The Principal Investigator and each individual delegated to obtain or receive de-identified data directly from DMH/DD/SAS through this request as a member of the investigator’s team must sign below acknowledging her/his responsibilities. **The Principal Investigator is responsible for the compliance of all members of her/his research team**:1. **I understand that a Data Use Agreement between the DMH/DD/SAS agency disclosing or**

**providing access to the requested de-identified data and my organization must be fully executed before I can access or receive the requested data**1. **I am aware that the de-identified data to which I have requested access is subject to Health Insurance Portability and**

**Accountability Act of 1996 and implementing regulations (HIPAA), the North Carolina Controlled Substances Reporting System Act and implementing regulations, and other legal and regulatory protections and that violation of privacy and confidentiality protections for this data may result in civil and criminal penalties.*** **I am aware that the study must be submitted to DMH/DD/SAS for a review prior to publication**
1. **I understand and agree to comply with the obligations listed in this section as well as with all obligations**

**described for the boxes I have checked above, and to inform all research team members of their responsibilities for compliance with these obligations.** |
| **Principal Investigator:** |
|  **Print Name Signature Date** |
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| Research study members delegated to directly obtain or receive the de-identified health information from DMH/DD/SAS through this request (if not the Principal Investigator): |
|  **Print Name / Role Signature Date** |
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| **SECTION IV DMH/DD/SAS APPROVAL**  |
| **DMH ID Number:**  |
| **(**xxxUUUmmddyyyy) - project (xxx), requester (UUU) and date |
| **Print Name Signature** |
| **Title** |
| **Date** |
|  |
| **SECTION V**  |
| 1. **DE-IDENTIFIED HEALTH INFORMATION**
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| De-identified health information **may not include** any of the following direct identifiers of the patient.  |
| * Names
* Geographic subdivisions smaller than a state
* ZIP codes (except first three digits **if** the combined population of all ZIP codes beginning with those three digits is **greater than 20,000)**
* All elements of dates except year (i.e., month/day; however, year must be excluded for patients age 90 and older) directly related to a patient, including birth or death or dates of health care services or health care claims
* Telephone numbers
* Fax numbers
* Electronic mail addresses
* Social Security Numbers
 | * Medical record numbers
* Health plan beneficiary identifiers
* Account numbers
* Certificate/license numbers
* Vehicle identifiers and serial numbers, including license plate numbers
* Medical device identifiers and serial numbers
* Web universal resource locators (URL)
* Internet protocol (IP) address numbers
* Biometric identifiers, including finger and voice prints
* Full face photographic images
* Any other number, characteristic, or code that could be used by the researcher to identify the patient
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| **Note:** Although de-identified health information cannot contain a birth date, it **may** contain the patient’s age expressed in years, months, days, or hours, as appropriate, except for patients who are aged 90 years or more. For persons aged 90 years and above, the age in de-identified health information can only be stated as being within the category of age 90 or above. |