**REQUEST FOR WAIVER OF HIPAA AUTHORIZATION**

**Study Title:**

**Principal Investigator/Project Leader**:

**Description of Study**

**List of Protected Health Information to be Accessed/Disclosed and Sources <Delete sources that are not needed>**

* **Arizona Health Care Cost Containment System (AHCCCS) health claims data**. AHCCCS is the state Medicaid provider. The data include health care transactions (claims) on all members, patients receiving inpatient, emergency department, or other outpatient care in the state. The data layout is already at the individual patient level when received by CHiR and requires no further manipulation to match patients. The data are collected under an individual data sharing agreement which includes HIPAA protections for the protected health information.
* **El Rio Community Health Center & Mountain Park Health Center Electronic Medical Records.** Both facilities are FQHCs and they are part of the health care safety net in Arizona. The data include health care encounters (visits) on all patients receiving outpatient care in the centers. The data layout is in the Common Data Model format for standardizing. The data are collected under an individual data sharing agreement which includes HIPAA protections for the protected health information.
* **Arizona Department of Health Services (ADHS) Vital Records**. The Bureau of Vital Records provides vital records (registered birth or death certificates from county offices statewide. Vital records data are Personally Identifying Information (PII) and Protected Health Information (PHI) data which are governed by Arizona Public Records laws and the Arizona statutes. The ADHS Human Subjects Review Board has final oversight over release of these records for research projects. CHiR collects vital records information annually from ADHS under an agreement for sharing of public health data.

The data to be accessed includes the following PHI:

* + Name
  + Address
  + Date of birth
  + Other full dates (admission, discharge, death, procedure, etc.)
  + Telephone number
  + Social security number
  + Medical record number/Health plan beneficiary number (AHCCCS ID)
  + Claim ID

Date Range: \_\_\_\_\_\_

The data to be disclosed to the requesting organization will be \_\_\_\_\_\_\_\_\_\_\_\_

**Methods to Secure Protected Health Information from Unauthorized Use and Disclosure**

* **Indicate where the PHI will be stored and who will have access**

For the Protected Health Information (PHI) in this study, its access/disclosure is governed by an agreement with the \_\_\_\_\_\_\_\_\_\_\_, which requires us to comply with all HIPAA/HITECH regulations. CHiR also maintains internal policies and procedures to protect the data stored in its repositories.

The data will be securely received and stored electronically in a dedicated computing infrastructure for research and administration of health related information at ASU’s University Data Center, which is maintained by ASU’s University Technology Office (UTO). The infrastructure is firewalled from the rest of the campus network and follows the industry best practice in operation of the environment to meet HIPAA compliance requirements.

The stored data will only be accessible by authorized CHiR data management staff through password-authenticated access. The authorized staff are regularly trained in local and federal confidentiality standards. Data will not be stored on individual computers or other media.

**Privacy Risks and Benefits**

* **Describe how the use or disclosure of PHI involves no more than minimal risk to the privacy of individuals.**
* **Describe how the privacy risks to the individuals who’s PHI will be accessed or disclosed is reasonable in relation to the anticipated benefits of the study, if any.**

The studies are minimal risk as no PHI will be disclosed to the research team. Only a de-identified data set will be provided to \_\_\_\_ for analysis and dissemination of the results. The researchers will have no ability to link the data set to any individual or group of individuals in the data. All results will be presented at the aggregate level. No attempts will be made to identify individuals.

There are no direct benefits to the individuals whose data will be accessed in this study.

**Describe how the waiver will not adversely affect the privacy rights and welfare of the individuals involved.**

All individuals whose PHI is accessed in this study will retain the privacy rights guaranteed to them under applicable federal, state, and other laws. No health care treatment or other welfare will be withheld or otherwise adversely affected by their participation in this study.

**Retaining Data and Identifiers**

* **Describe the plan to destroy the identifiers at the earliest opportunity**

The identifiers will remain with the data that is collected from \_\_\_\_\_ in CHiR’s repository. Repository data will be retained until it is no longer relevant to the business.

The information provided to the requesting organization will only be \_\_\_\_\_\_\_\_\_\_\_\_

**How “Minimum Necessary” Rule Is Applied**

The HIPAA minimum necessary rule is applied to this study by only providing the requesting organization with anonymous results. This is all that is needed to accomplish their study goals and no PHI will be removed from CHiR’s secure environment.

Need for Waiver of Authorization

* Describe how the research could not practically be conducted without the waiver
* Describe how the research could not practically be conducted without access to and use of PHI

The research cannot be conducted without a HIPAA Waiver of Authorization as the authorized CHiR staff will need to access the full PHI data, which is received and stored in fully identifiable format, in order to extract the \_\_\_\_\_ for this study. The data contains PHI on millions of persons receiving health care in Arizona. The patients contained in the data are unknown, and it is not practical to contact such a large volume of patients to seek authorization as many may have changed addresses or moved out of state.

The \_\_\_\_\_\_ data is the only complete data source of health claims for \_\_\_\_\_\_ in Arizona; therefore, the researchers cannot conduct this study without this data source.

**Assurances**

* I certify that the information provided in this request for Waiver of HIPAA Authorization is complete and correct.
* I assume responsibility for the protection of the privacy rights and welfare of human subjects and the ethical conduct of this research study protocol.
* I will comply with all applicable federal, state, and local laws and internal policies and procedures regarding the protection of human subjects in research.
* I will securely maintain any PHI collected for this study and will not disclose the information to any individual or entity outside those listed in the protocol except as required by law.
* I will make no attempt to re-identify the participants from the data collected under this waiver, and not attempt to contact the participants or their family members.

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Signature of Project Leader Date

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Signature of CHiR Administrator/HIPAA Privacy Officer Date

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Signature of CHiR Data Manager/HIPAA Security Officer Date