

## **HAC Policies and Procedures**

### **HIPAA, the Privacy Board and the HAC**

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#### **What is HIPAA?**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated regulations that govern privacy, security, and electronic transactions standards for health care information including research related information.

#### **What Does HIPAA Require?**

HIPAA requires:

1. Standardization of electronic patient health, administrative and financial data.
2. Unique identifiers for individuals, employees, health plans and health care providers.
3. Security standards protecting the confidentiality and integrity of health information.

The Privacy Rule of HIPAA was published on August 14, 2002 and became effective April 14, 2003. The Privacy Rule established privacy standards protecting protected health information (PHI) of an individual, including research activities. These privacy regulations affect researchers and the HAC as well as carries stiff civil and criminal penalties for improper disclosure and/or use.

#### **Who Serves as the Privacy Board for MCG, MCGHI and the Augusta VAMC for Research Issues?**

The HAC also serves as the Privacy Board for the Medical College of Georgia (MCG), MCG Health, Inc., (MCGHI) and the Augusta Veterans Affairs Medical Center (VAMC).

#### **Because The HAC Serves As The Privacy Board As Well As The IRB, Do They Consider One Set Of Criteria Over The Other?**

On a case-by-case basis the HAC considers both sets of criteria before determining whether informed consent and authorization for the research can be waived. These conditions must be met so that the HAC may:

1. Waive the requirement to obtain consent in accordance with applicable regulations
2. Permit waiver or alteration of an element of informed consent
3. Waive documentation of informed consent are allowed in accordance with applicable regulations

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The Common Rule allows the HAC to approve research in which informed consent is obtained orally from subjects under limited circumstances. Typically, scripts are required (especially if non-medically trained staff will be obtaining oral consent) and must be submitted for HAC approval. Ideally, some written study information is provided to the subject during his/her participation in the research.

The Privacy Rule allows a waiver or alteration of the written authorization requirement. Researchers obtaining oral consent may obtain oral authorization as well if the waiver of authorization criteria listed above is met.

### **What is Protected Health Information (PHI)?**

PHI is defined as:

1. Names
2. Geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial 3 digits of the zip code if, according to the current policy available from the Bureau of the Census:
  - a. The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; AND
  - b. The initial 3 digits of the zip code for all geographic units containing 20,000 or fewer people is changed to 000.
3. Dates (except year) directly related to an individual (e.g., date of birth, discharge date, date of death) and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 80 or older
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers

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11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web universal research locators (URL)
15. Internet protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images (printed or video); and
18. Any other unique identifying number, characteristic or code

### Databases

A database, that is used for tracking purposes such as board certification requirements or The Joint Commission (TJC – formerly known as JCAHO) requirements and/or research purposes, can be created and maintained and be compliant with HIPAA at the same time. These are the criteria:

- Submit a master protocol wherein informed consent and HIPAA authorization are obtained at the outset for entry and use of information in the various subsequent protocols. This type of protocol will require full Committee Review.
- Each time that the investigator queries the database as outlined in the above paragraph to obtain information that may be used for publications and research, a protocol must be prospectively submitted to and approved by the HAC. Such protocols may be approvable under the expedited criteria review since informed consent and authorization have already been obtained.

Several questions have arisen since the HIPAA Privacy Rule Implementation. Two are posted below for clarification regarding the use of databases.

### **Does The HIPAA Privacy Rule Permit The Creation Of A Database For Research Purposes Through An Institutional Review Board (IRB) Or Privacy Board Waiver Of Individual Authorization?**

Yes. A covered entity may use or disclose protected health information without individuals' authorizations for the creation of a research database, provided the covered entity obtains documentation that an IRB or Privacy Board has determined that the specified waiver criteria were satisfied. Protected health information maintained by a covered entity in such a research database could be used or disclosed for future research studies as permitted by the Privacy Rule - that is, for future studies in which individual

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authorization has been obtained or where the Rule would permit research without an authorization, such as pursuant to an IRB or Privacy Board waiver.

### **Can Researchers Continue To Access Existing Databanks Or Repositories That Are Maintained By Covered Entities, Even If Those Databases Were Created Prior To The Compliance Date Without Patient Permission Or Without A Waiver Of Informed Consent By An Institutional Review Board (IRB)?**

Yes. Under the HIPAA Privacy Rule, covered entities may use or disclose protected health information from existing databases or repositories for research purposes either with individual authorization as required at 45 CFR 164.508, or with a waiver of individual authorization as permitted at 45 CFR 164.512(i).

### **Medical Records**

There is a provision in the regulations that will allow a researcher to review protected health information (PHI) for the purpose of preparing a protocol or similar purposes, which are considered to be "preparatory to research". For those entities that utilize the Human Assurance Committee (HAC) as the IRB such as MCG, MCG Health Systems (MCGHI), and the Augusta Veterans Affairs Medical Center (VAMC), authorization to gain access to PHI, including for review preparatory to research is required. Such authorization and the scope of the information to be accessed shall be limited to only that information necessary to make a determination as to the practicality of the final study.

### **As A Physician, I Have Been Contacted By A Health Care Insurer Who Wishes To Obtain Performance Data Or Registry Data On My Patients. Can I Send Them The Records Or Can They Send Someone Here To Review The Records?**

No. This is a research study and must be submitted to the HAC for approval prior to releasing any information. As a general business practice, the Health Information Management Services (HIMS) at MCGHI does not allow this information to be released as it is not required.

### **As A Physician, I Have Been Contacted By An Individual (Student From Another School, Etc.) Who Is External To Our Research Community (MCG, MCGHI Or The Augusta VAMC). Can They Come In And Review My Patient's Records?**

No. Again, this is a research study and must be submitted to the HAC for approval prior to releasing any information. As a general business practice, the HAC does not allow external individuals to have access to this data unless there is a local PI and other regulations have been addressed.