OHRP Policy
Retrospective and Prospective Chart Reviews

1.0 Definitions

**Retrospective chart review** - evaluates patient data that is existing at the time the protocol is submitted to the IRB for initial approval. This type of chart review uses information that has usually been collected for reasons other than research, such as administrative data and medical records. Therefore, the outcome of interest has already occurred by the time the study is started.

**Prospective Chart Review** – evaluates patient data that **does not yet exist** at the time the protocol is submitted to the IRB for initial review. The protocols are designed before any information is collected. Study subjects are identified and followed forward to see if the outcome of interest happens over time.

2.0 Approval Categories for Retrospective Chart Reviews

**Expedited Review:**
Retrospective and Prospective chart reviews may qualify for expedited review according to 45 CFR 46.110 category 5 if:

a. The research involves no more than minimal risk or minor changes in approved research; **AND**
b. The research involves materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as for medical treatment or diagnosis). The expedited review procedure may not be used for studies in which identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

**Full Board Review:**
Retrospective medical chart review studies that do not meet the criteria outlined in categories 1 and 2 must be approved by the fully convened IRB. Examples of such studies might be those in which the information contained in the medical records is of a sufficiently sensitive nature that additional safeguards are necessary to protect subjects’ rights.

3.0 Types of Consent for Chart Reviews

**Waiver of Consent Process:** Waiver of consent process is the most frequently requested type of consent for both retrospective and prospective chart reviews. In order for the IRB to approve a waiver of consent process, the IRB must be satisfied that the following criteria are met:

A. The research involves no more than minimal risk to the subjects;
B. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
C. The research could not practically be carried out without the waiver or alteration; and
D. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

For more information regarding waiver of consent, please see the HAC Policy: Waiver of Consent
Waiver of Documentation of Consent: This type of consent is not usually requested for a chart review. Under a waiver of documentation of consent, an investigator must still obtain consent from the subject. However, the investigator does not need to obtain a signed consent form from subjects if the IRB agrees that the following criteria are met:

A. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

B. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

For more information regarding waiver of consent, please see the HAC Policy: Waiver of Consent.

Written Consent: In certain instances the IRB may determine that written consent is required if the investigator is unable to justify why it’s impracticable to conduct the research without a waiver. This is more often the case for prospective chart review studies, but sometimes occurs in retrospective chart review studies. For example, an investigator wants to conduct a study that would include the review of the charts of all of her clinic patients who have a history of mental illness. The IRB may determine that the investigator should obtain prior written consent from each patient.

4.0 Request for Waiver of HIPAA

A Waiver of Authorization of HIPAA does not mean your research is exempt from HIPAA’s privacy regulations. It only means you do not need signed authorization from each research subject.

To qualify for Waiver of HIPAA Authorization, investigators should indicate that:

- The research use of the health information does not represent more than a minimal risk to privacy
- That the research could not be done without the requested health information
- That it would not be practical to obtain signed authorizations from the research subjects
- That the specific elements of health information that are requested are not more than the minimum necessary to accomplish the goals of the study.

The IRB will review the Waiver Request at either a full board meeting or through expedited review, consistent with the review process for the research application. If approved, the Waiver of HIPAA Authorization will be documented in the protocol initial approval letter.

Studies that involve a Waiver of Informed Consent and that are approved by the IRB on or after April 14, 2003, must also have a Waiver of Authorization of HIPAA approved by the IRB.

For studies that the IRB approved with Waiver of Informed Consent before April 14th, 2003 no Waiver of Authorization for HIPAA is required.

5.0 Additional Requirements

For Studies that have been granted waiver of informed consent/waiver of HIPAA authorization, and are accessing GHSU hospital medical records the following must be done:
The research team member must log each medical record accessed in the disclosure tracking module at:
http://hi.georgiahealth.edu/hipaa/

For complete hospital policy information see the following links:
http://hi.georgiahealth.edu/aboutus/PDFPolicies/05_02.pdf
http://hi.georgiahealth.edu/aboutus/PDFPolicies/06_08.pdf
http://hi.georgiahealth.edu/aboutus/PDFPolicies/06_17.pdf

If you have additional questions related to these policies or the disclosure tracking log, please contact Melissa Jarriel, RHIA, CTR, CHP, Director, Health Information Management Services at 706 721-2722.

6.0 Proper Data Storage for Research

As part of your research protocol, you must request secure file storage for you and your research team to store research data electronically. This is included in the submission of new protocols. GHSU requires that all such data be stored in an ITSS managed secure location that would protect it from a breach of confidentiality, loss, theft, or inappropriate modification.

For any questions regarding secure server space, please see the ITTS web page:
http://georgiahealth.edu/itss/networking/index.html