UNIVERSITY OF TENNESSEE
GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
CASE STUDIES/REPORTS

I. PURPOSE

To document the procedures used by University of Tennessee Graduate School of Medicine Institutional Review Board to review and evaluate submissions for the use of case studies/reports.

II. SCOPE

This SOP applies to the IRB administrative staff, Board members, and investigators.

III. BACKGROUND

Federal regulations for the protection of human subjects define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A case study/report or the retrospective review of medical/dental records involving data from five or less patients does not involve a systematic investigation or contribute to generalizable knowledge. However, IRB review and approval is required. The review of medical/dental records involving six or more patients does require IRB review and approval, as this represents a systematic collection of data that will contribute to generalizable knowledge.

Under HIPAA, if the case study/report or retrospective review of medical/dental records involving five or less patients includes one or more of the 18 identifiers, then the investigators who wish to publish the case study/report will need to obtain a signed HIPAA compliant authorization from the patient or legally authorized representative (LAR). However, if the HIPAA identifiers are removed from the data prior to submission and publication of the article, then there is no need to obtain a signed privacy authorization.

In Accordance With:

45 CFR 46.101(b) and 46.102(d) and (f); and 45 CFR 160, 164;
http://www.hhs.gov/ocr/hipaa

Human Subject
http://grants.nih.gov/grants/policy/hs/specimens.htm

Human Subjects Research – Human Specimens, Cell Lines or Data FAQs
http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm

OHRP – Guidance on Research Involving Coded Private Information or Biological Specimens
http://www.hhs.gov/ohrp/policy/cdebiol.html

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. UTGSM investigators who prepare a case report/study or who review medical/dental records involving data from five or less patients should fill out a Case Report form and submit one copy to the IRB office. The Case Report form can be found on the IRB website or can be obtained by calling the IRB office. If the case study/report or retrospective review of medical/dental records includes one or more of the 18 identifiers (see below), then the investigators who wish to publish the case study/report will need to obtain a signed HIPAA compliant authorization from the patient or legally authorized representative (LAR). Alternatively, if the HIPAA identifiers are removed from the data prior to submission and publication of the article, then there is no need to obtain a signed privacy authorization.

2. Residents, Fellows or any Trainee of any discipline who are submitting Case Reports must complete the CITI course.

3. The review of medical/dental records involving six or more patients requires IRB review and approval. See *SOP: UTGSM IRB Exemption from IRB Review: Determination*, and *SOP: UTGSM IRB Expedited Review*.

List of 18 HIPAA Identifiers

1. Names

2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, 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 90 or older;

4. Phone numbers;
5. Fax numbers
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)