

**OKLAHOMA STATE UNIVERSITY
CENTER FOR HEALTH SCIENCES**

ACCOUNTING FORM

Subject: **Research Involving Disclosures About 50 or More Individuals** *(To Be Used Only In Studies Where the IRB Has Granted a Waiver of Authorization)*

Date: **April 14, 2003**

The Privacy Regulations issued under the Health Insurance Portability and Accountability Act (“HIPAA”) require that researchers account for all disclosures that they make of protected health information (“PHI”) in certain types of research (where authorization has been waived by IRB, research on decedents and reviews preparatory for research). A disclosure is sharing PHI with someone outside the Oklahoma State University Center for Health Sciences (“OSU-CHS”) workforce. For research where the IRB has determined to waive individual authorization, this simplified form is available for accounting for these disclosures.

This form should be used only where the OSU-CHS IRB has granted a waiver of authorization for use or disclosure of the patient/participant’s PHI for waived research projects involving disclosures about 50 or more individuals. Part I of this form must be filled out and the form submitted with the initial application for the study. Part II of this form tells you about your responsibility to provide information to the IRB if a request for accounting of disclosures is made by an individual.

PART I:

Study Title: _____

Provide the following information to the IRB with the initial application for the study:

1. Briefly describe the study, including the purpose of the study and the criteria for selecting particular records: _____

2. Briefly describe the PHI to be disclosed: _____

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3. The date or period of time during which the disclosures are likely to occur: _____
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4. The name, address, and telephone number of the entity that sponsored the study and of the outside researchers to whom the PHI likely will be disclosed: _____
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PART II:

The Researcher Must Provide the Following Information if the IRB Receives a Request for an Accounting of Disclosures Made During the Course of Research:

If the IRB or the OSU-CHS Privacy Officer receives a request by an individual for an accounting of disclosures that were made relating to the individual over a given period of time (the “accounting period”), the IRB or the OSU-CHS Privacy Officer will ask the researcher to state, to the extent possible, the following:

- The date or period of time during which the disclosures in the study occurred, including the date of the last such disclosure during the accounting period.
- Whether the individual’s PHI may or may not have been disclosed in the study during the accounting period.

These inquiries will be made to the researcher by the IRB or the OSU-CHS Privacy Officer after the individual requests an accounting. The researcher’s answers to the above questions will be in needed to provide the individual with the accounting. The accounting must be provided within 60 days after the request is made. Please provide your information to the IRB or the OSU-CHS Privacy Officer within 45 days of the request so the information can be organized in a proper manner to provide to the individual who requested the accounting.

NOTE: If it is reasonably likely that the individual’s PHI was disclosed during the study, the IRB or the OSU-CHS Privacy Officer must, at the request of the individual, assist in contacting the entity that sponsored the study and the outside researchers. The IRB will ask for the researcher’s help in providing this information to the individual.

After Part A of this form is completed, submit the form to OSU-CHS IRB Administrator.