


SUBJECT: Human Research Billing	DATE: 1/2/06	Pages: 3
	APPLICATION: ACHRI	
	DISTRIBUTION:	
	APPROVED BY: 	
RECOMMENDED: Janet Storment, RN, CCRC Clinical Trials Administrator	SUPERSEDES: None	

**PURPOSE**

The purpose of this policy is to set forth criteria for billing for services provided to participants in ACHRI Clinical Trials.

**Abbreviations and Definitions**

Clinical Trial: A systematic investigation of the effects of materials (e.g., investigational drugs, devices, biologics) or methods (e.g., surgery, radiation) conducted according to a study plan (protocol) that prospectively assigns human subjects to intervention and/or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome (including Pharmokinetic and Pathology studies).

Investigator: The person held responsible for the conduct of a specific research study at an investigative site. If a research study is conducted by a team of individuals at an investigative site, the investigator is the responsible leader of the team and may be called the principal investigator (PI)

ACH: Arkansas Children's Hospital

ACHRI: Arkansas Children's Hospital Research Institute

AHRQ: Agency for Healthcare Research and Quality

CDC: Centers for Disease Control

Clinical Trial NCD: Clinical Trial National Coverage Decision

CMS: Centers for Medicare and Medicaid Services

DOD: Department of Defense

Investigational Product: A pharmaceutical product, placebo or device being used in an investigational clinical trial.

IRB: Institutional Review Board

NIH: National Institutes of Health

STS: Subject Tracking System

Sponsor: A person or an organization that funds or plans and carries out a project and/or activity.

### **Criteria for Differentiation Between Research Charges vs. Standard Medical Practice Charges**

The Principal Investigator (PI) or his/her designee is responsible for appropriate and accurate billing for each clinical trial. **All charges related to the clinical trial must be charged to the research account unless they are associated with procedures that may be billed to third party payers or the subject by applicable state and federal statutes, rules and regulations for care that would be ordinarily provided for a patient absent any research program. It is the PI's responsibility to differentiate these charges and document sufficiently to justify the medically necessity of the care.**

#### **PROCEDURES**

When a procedure is required by the clinical research protocol that would be performed regardless of subject's participation in the research study, that procedure may be billed to the subject or his/her third party payer. When determining that a procedure is standard medical practice, always have objective back-up: national guidelines and recommendations; credible medical literature, etc.

#### **CLINICAL TRIALS THAT ARE SPONSORED BY NIH, CDC, AHRQ, CMS, AND DOD:**

Research procedures may qualify for billing to insurance, a third party payer, or the subject if the protocol is deemed a qualifying clinical trial by the Clinical Trials NCD. Go to [www.cms.hhs.gov/coverage/8d2.asp](http://www.cms.hhs.gov/coverage/8d2.asp) for more information about qualifications.

#### **DEVICES**

The sponsor must have FDA approval or letter of exemption before the investigator can charge a research subject for an investigational product (i.e. devices). The FDA informed consent regulation {21 CFR 50.25(b)(3)} explains the requirement that the informed consent must state what, if any, additional costs the subject will incur by participating in the clinical trial.

#### **CONFLICTS**

Should a conflict arise as to the definition and/or applicability of a procedure to standard medical practice, the procedure will be billed to the research account, unless the PI can demonstrate that the procedure falls within the normal standard medical practice for the patient population. This conflict may be discovered during the budgeting process or during the course of the clinical trial or as a result of an audit by the ACH Internal Audit Department or a third party payer.

#### **PAYMENT FOR STUDY SUBJECT MEDICAL INJURY**

In the event a subject who has consented to participate in an industry sponsored clinical trial should require additional medical or surgical care as a consequence of the study, the Sponsor

must provide payment for those medical expenses incurred by the subject. If it is determined by the investigator that the injury is not study related the medical expenses incurred may be billed to the insurance, third party payer and/or the subject.

CLINICAL TRIALS THAT ARE SPONSORED BY NIH, CDC, AHRQ, CMS, AND DOD- The decision on how to bill for medical expenses incurred as a result of a study-related injury will be made on a case by case basis by the investigator and ACHRI. In these circumstances the consent form must clearly inform the subject of their possible financial obligations.

## **ADDITIONAL EXPENSES**

**If additional unexpected expenses arise during the performance of a clinical trial, please contact the Clinical Trials Administrator.**

After an ACHRI account has been established, only charges specifically outlined in the clinical trial budget may be charged.

### **Subject Tracking System**

The Subject Tracking System (STS) is designed to be a secure, accurate and independent record of the procedures that were performed on subjects who are part of a specific clinical trial. This independent record is then used by the Clinical Trials Administrator and Patient Accounts to ensure proper billing. The benefit of STS to the clinical trial is that the Clinical Trials Administrator will assure that those charges confirmed through STS will be the exact charges that are charged to the clinical trial account. This will remove the need for a lengthy and complicated reconciliation of the account by the investigator.

STS must be used for all clinical trials with billable procedures.

When a subject has been enrolled in the clinical trial the PI or his/her designee will enroll the subject in STS then enter a visit including all procedures completed at that visit. These procedures will then be verified with Meditech and authorized for payment by the Clinical Trials Administrator on a monthly basis. If there is a discrepancy between Meditech and STS, the Clinical Trials Administrator will work with the PI or his/her designee to resolve the issue.

It is the responsibility of the PI or his/her designee to ensure that each subject participating in the research project is registered in Meditech, and is assigned a research account number that is tied to the appropriate study mnemonic. All research-related procedures are then charged to this specific account.

Other policies to be referred to:

1. Private Industry Sponsored Clinical Trials Policy (6/17/05)
2. Unfunded/Under-Funded Human Research (6/17/05)
3. ACHRI Research Awards Policy (4/2/04)