

# UConn HEALTH

POLICY NUMBER 2006-09  
November 8, 2011

**POLICY: ESTABLISHMENT OF A BILLING EMPLOYER ACCOUNT NUMBER (BEAN), AND INDIVIDUAL “CASE NUMBER” FOR CLINICAL RESEARCH/TRIAL PATIENTS**

**PURPOSE:**

The purpose of this policy is to define the mechanism whereby researchers and/or study coordinators will obtain a study Billing Employer Account Number (BEAN) for new clinical trials/research in order to establish the study in the institutional billing system. A BEAN account must be established prior to accruing patients to any research trial or protocol. If a PI fails to obtain a BEAN account number in a timely fashion, the Associate Dean for Clinical Research and Planning will ask the Director of the Human Subjects Protection Program to close the study to accrual until the PI obtains a BEAN number. Furthermore, the PI will be asked to submit an action plan to prevent future non-compliance with this policy.

The researchers will also obtain an individual research study patient “Case Number” to identify all patients who are participating in a clinical research trial to all departments within the institution and to establish a charging/billing mechanism for all Protocol Induced Costs (PIC) of designated research studies/clinical trials. The Case Number must be obtained before protocol induced research services are incurred. A Case Number cannot be issued if the study does not have a BEAN number.

**SCOPE:**

This policy applies to all clinical research projects involving research induced medical interventions and research-related patient charges generated from medical, behavioral, social science, outcomes and health services research involving human subjects conducted within UConn Health.

**POLICY STATEMENT:**

It is the policy of UConn Health to have a procedure in place to:

1. Assign a BEAN to all new clinical research/clinical trials that include billing of patient services.
2. Identify patients who are participating in clinical research and obtain a unique “Case Number” prior to the initiation of any services related to the research study/clinical trial. This will ensure that all PIC associated with the clinical research/ trial are properly delineated from Routine Costs (RC) and billed appropriately to the research sponsor.

[Hyperlink to procedure to obtain a BEAN and “Unique Patient Case Number”](#)  
[Hyperlink to Determination Schema](#)

**DEFINITIONS:**

**Clinical Research:**

- A. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes:
  - Mechanisms of human disease
  - Therapeutic interventions
  - Clinical trials
  - Development of new technologies
- B. Epidemiologic and behavioral studies
- C. Outcomes research and health services research.<sup>1</sup>

**Clinical Trial:** A clinical trial is a systematic, organized, prospective intervention study in human subjects that is conducted according to a formal study plan (protocol) and that has measurable efficacy and/or safety-related outcomes that are amenable to statistical analysis. It employs one or more intervention technique(s) including prophylactic, screening, diagnostic, or therapeutic agents, devices, or procedures. It must have approval of the IRB or review with a determination of exemption. Clinical trials are distinguished from other types of clinical research (e.g., behavioral research) that may need IRB approval but do not meet the other criteria of clinical trials.<sup>2</sup>

**Principal Investigator (PI):** The researcher with overall responsibility for the direction of a research project, grant or contract. A medical professional who is overseeing the treatment of subjects in the clinical trial.

**Study Coordinator:** The member of the research team, who manages the daily activities of the study, including coordinating the treatment or testing of participants. Study Coordinators are also responsible for such things as, recruiting, screening, and enrolling study participants, as well as ensuring the adherence to Good Clinical Practice.

**Sponsor:** The entity (e.g., pharmaceutical company, National Institutes of Health (NIH), National Cancer Institute (NCI), private foundation, individual investigator, etc), that is the originator and/or financier of the clinical trial protocol that is being administered by the PI.

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<sup>1</sup> National Institutes of Health (NIH), panel on Clinical Research 1995

<sup>2</sup> Adapted from Emory University, Association of Academic Health Centers (AAHC), 2004

Peter Albertson (Signed)

11/17/11

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**Associate Dean, Clinical and Translational Research**

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**Date**

Philip Austin (Signed)

11/21/11

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**Vice President for Health Affairs**

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**Date**

New Policy: 6/23/06  
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