UCONN HEALTH

POLICY NUMBER 2009-05
November 20, 2009

POLICY: INSTITUTIONAL DISCOUNTS FOR INVESTIGATOR-INITIATED CLINICAL TRIALS

PURPOSE:
To encourage researchers at UConn Health to engage in investigator-initiated clinical research.

SCOPE:
This policy applies to all investigator-initiated clinical research projects involving research induced medical interventions and research-related patient charges for UConn Medical Group (UMG) professional fees and/or John Dempsey Hospital (JDH) hospital charges generated from medical, behavioral, social science, outcomes and health services research involving human subjects conducted within UConn Health.

POLICY STATEMENT:
This policy supports an agreement between UConn Health and sponsors of Clinical Trials that affirms there will be given a uniform, stated discount to Principal Investigators engaging in investigator-initiated research, and that charges to which the discount will be applied will remain constant for a period for three years, commencing September 1, 2009.

DEFINITIONS:
Clinical Research:
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
- Epidemiologic and behavioral studies
- Outcomes research and health services research [1]

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[1] National Institutes of Health (NIH), panel on Clinical Research 1995

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 Measureable efficacy and/or safety-related outcomes that are amenable to statistical analysis. It employs one of more intervention techniques(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.[2]

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.

Peter Albertsen (signed) 12/14/09

Associate Dean, Clinical Research Planning and Administration Date

Bruce Koeppen (signed) 12/17/09

Dean for Academic Affairs Date

Cato T. Laurencin (signed) 12/17/09

Vice President for Health Affairs Date

NEW POLICY: November 20, 2009

[2] Adapted from Emory University, Association of Academic Health Centers (AAHC), 2004