University of Connecticut Health Center
School of Dental Medicine

Policy Number 2012-3

POLICY: Dental Clinical Research/Discounts for industry sponsored Research

October 31, 2012

PURPOSE:
To encourage clinical researchers at the University of Connecticut Health Center to engage in industry sponsored clinical research.

SCOPE:
This policy applies to all industry sponsored clinical research projects involving dental clinical research interventions and research-related charges generated from medical, behavioral, social science, outcomes and health services research involving human subjects conducted by School of Dental Medicine (SDM) faculty within the SDM, Dental Clinical Research Center (DCRC), and Center of Implant and Reconstructive Dentistry (CIRD).

POLICY STATEMENT:
This policy supports a uniform, stated discount to Principal Investigators engaging in industry-sponsored research. Industry sponsored studies are restricted to DCRC and CIRD.
For research within the DCRC, the procedural charges will be discounted at 20% of the University Dentists (UD) fees, i.e. procedure fees set at 80% of prevailing UD fees. For research within the CIRD, the procedural charges will be discounted at 10% of the UD fees, i.e. procedure fees set at the 90% of prevailing UD fees. Industry-sponsored clinical studies are not allowed in UCHC Dental Clinics.

DEFINITIONS:
Clinical Research:

A. Patient-oriented research conducted with human subjects (or material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. The 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[1].

Clinical Trial: A clinical trial is a systematic, organized, prospective intervention study in human subjects that is conducted according to a formal study protocol and that measurable efficacy and/or safety-related outcomes that amenable to statistical analysis. It employs one or more intervention techniques including prophylactic, screening, diagnostic or therapeutic agents, devices, or procedures. It must have the approval of the IRB or review with determination of exemption.

Principal Investigator (PI): The researcher with overall responsibility for the direction of a research project, grant or contract.

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 Institute of Health (NIH), National Cancer Institute (NCI), private foundation, etc.) that is the originator and/or financier of the clinical trial protocol that is being administered by the PI.

Effie Ioannidou, DCRC Director — Date: 11/27/12

Susan Reisine, Associate Dean for Research — Date: 11/27/12

R. Lamont MacNeil, Dean — Date: 11/27/12

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