



University of Connecticut Health Center  
*School of Dental Medicine*

**Policy Number 2012-2**

**POLICY: Dental Clinical Research/Discounts for Investigator-Initiated Research**

**October 31, 2012**

**PURPOSE:**

To encourage clinical researchers at the University of Connecticut Health Center to engage in investigator-initiated clinical research.

**SCOPE:**

This policy applies to all investigator-initiated 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 UCHC Dental Clinics.

**POLICY STATEMENT:**

This policy supports a uniform, stated discount to Principal Investigators engaged in investigator-initiated research. Based on this policy, for research within DCRC or the UCHC Dental Clinics, the procedural charges will be discounted at 45% of the University Dentists (UD) fees, i.e. procedure fees set at 55% of prevailing UD fees.

For research within the Center of Implant and Reconstructive Dentistry, the procedural charges will be discounted at 35% of the UD fees, i.e. procedure fees set at the 65% of prevailing UD fees.

In the student and resident Dental Clinics, industry funded investigator-initiated studies are set at 55% of prevailing UD fees. No research studies supported by state and/or federal funding are permitted within the UCHC student and resident 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<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 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.



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Effie Ioannidou, DCRC Director

12/18/12

Date



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Susan Reisine, Associate Dean for Research

12/20/12

Date



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R. Lamont MacNeil, Dean

12/18/12

Date

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