University of Connecticut Health Center
School of Dental Medicine

Policy Number 2012-4

POLICY: Dental Clinical Research/Routing Process

October 31, 2012

PURPOSE:
To ensure that all clinical investigators involved in dental clinical research are in compliance with institutional policies and regulations related to the budget routing process.

SCOPE:
This policy applies to all investigator-initiated and industry sponsored clinical research projects involving dental clinical research interventions involving human subjects conducted by SDM faculty within the SDM, the Dental Clinical Research Center (DCRC), the Center of Implant and Reconstructive Dentistry (CIRD) as well as the UCHC Dental Clinics.

POLICY STATEMENT:
Once the budget workbook is finalized by the Office of Clinical and Translational Research (OCTR) and the PI, the routing process will be initiated. Clinical trials sponsored or supported by Industry use the OCTR Statement of Commitments and Proposal Approval for Clinical Trials, to route the study. Clinical trials sponsored or supported by Federal or Foundation grants require the same form as above AND the first page of the Office of Research and Sponsored Programs (ORSP) routing form.
The routing process will start with the DCRC Director, who will review the budget workbook. Following the DCRC director signature, the proposal will be forwarded to the following offices for approval: Department Chair(s), the Associate Dean of Research and the Dean of the School of Dental Medicine and OCTR. Projects funded by Federal or Foundation grants must also be approved by Office of Research and Sponsored Programs. A CRC/DCRC letter of support will be provided only after the budget is approved by the DCRC Director.

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.

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

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

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

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