University of Connecticut Health Center
School of Dental Medicine

Policy Number 2012-1
POLICY: Dental Clinical Research/Trials Budget Review and Exemption
October 31, 2012

PURPOSE:
To ensure that all Principal Investigators (PIs), who participate in patient-oriented clinical research activities, including clinical trials, within the School of Dental Medicine (SDM) complete a Budget Workbook in compliance with all institutional policies and procedures in parallel with study contract negotiations and prior to the submission of the study to the Institutional Review Board (IRB).

SCOPE:
This policy applies to all 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 SDM faculty within the SDM, and UCHC.

POLICY STATEMENT:
The goal of the Budget Review Process is to allow the PI, Dental Clinical Research Center (DCRC) Director, Associate Dean for Research and the Department Chair to make an informed decision regarding institutional participation in a clinical research/trial project. The Clinical Research/Trials Budget Review process ensures that the projects comply with institutional policies as well as state and federal laws and regulations.
Prior to submission of a clinical study/trial to the IRB for review, the PI with the assistance of the research administrator, study coordinator and in collaboration with the Office of Clinical and Translational Research (OCTR), will prepare a budget using the pre-workbook packet including expected revenues from the sponsor and the direct and indirect costs associated with conducting and administering the trial. The pre-packet workbook, sponsor's budget, study protocol and the informed consent will be submitted to OCTR for review in order to complete the budget workbook for the study
During the budget workbook process services delineated by the PI as Protocol Induced Costs (PIC) and/or Routine Clinical Care (RC) will be validated by OCTR staff. Additional time and effort for research staff to complete administrative responsibilities and subject care will also be identified. After completion of the budget workbook, a completion memo will be attached to the IRB submission material.
If a study does not generate clinical charges, a letter of exemption will be issued by OCTR for the IRB submission.

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