UCONN HEALTH

POLICY NUMBER 2006-13
June 23, 2006

POLICY: HEALTH INSURANCE COVERAGE FOR CANCER CLINICAL TRIALS IN CONNECTICUT

PURPOSE:
To ensure adherence to the Connecticut General Statutes § 38a-504a through § 38a-504g and § 38a-469 when assessing eligibility and insurance coverage when billing third party payors for routine costs (RC) of a Cancer Clinical Trial.
https://www.cga.ct.gov/current/pub/chap_700c.htm

SCOPE:
This policy applies only to routine costs (RC) of a Qualifying Cancer Clinical Trial as described in the Connecticut General Statutes § 38a-504a through § 38a-504g and § 38a-469.

POLICY STATEMENT:
The University of Connecticut Health Center ensures that all Cancer Clinical Research studies are evaluated pursuant to Connecticut General Statutes § 38a-504a through § 38a-504g and § 38a-469 when assessing study qualifying status, patient eligibility and insurance coverage prior to billing third party payors for Routine Costs (RC) of a Cancer Clinical Trial.

This includes using the **standardized form found in sections 38a-504f and 38a -542f of the Connecticut General Statutes** when seeking to enroll an insured person in a cancer clinical trial and shall be accepted by every entity that provides coverage pursuant to sections 38a-504f and 38a -542f of the Connecticut General Statutes.
https://www.cga.ct.gov/current/pub/chap_700c.htm

DEFINITIONS:
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 measurable efficacy and/or safety-related outcomes that are amenable to statistical analysis. It employs one or more intervention technique(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.[1]

Principal Investigator:

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

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.

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 (GCP).

Sponsor: The entity (e.g., pharmaceutical company, National Institutes of Health (NIH), National Cancer Institute (NCI), private foundation, individual investigator, etc), that is the originator and/or financier of the clinical trial protocol that is being administered by the PI.

Bruce M. Koeppen, M.D. — 7/27/06
Dean for Academic Affairs — **Date**

Peter Albertsen, M.D. — 7/27/06
Associate Dean, Clinical and Translational Research — **Date**

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Executive Vice President for Health Affairs — **Date**

NEW POLICY: June 23, 2006