OFFICE OF CLINICAL TRIALS (OCT) QUICK REFERENCE SHEET

GENERAL CONTRACT INFORMATION
1. Official institution name:
   The University of North Carolina at Chapel Hill
2. Official name, title and address for University signature:
   Aylin Regulski, MS, JD, Associate Director, Office of Clinical Trials acting on behalf of
   Vice Chancellor for Research
   720 Martin Luther King, Jr. Blvd, CB# 1651
   Chapel Hill, NC 27599-1651
   Phone: (919) 843-7894
4. Federal Tax ID # 56-600-1393
5. Checks from sponsors are to be made payable to: The University of North Carolina at Chapel Hill
6. Checks should be mailed to the PI
7. IRB invoices will be generated & sent to sponsors by OCT.

F&A (FACILITIES AND ADMINISTRATION) COST RATES (EFFECTIVE 07/01/12 – 06/30/16)
Federal trials:
   52.0% at UNC, 28% within 10 miles, 26% remote (>10 mile radius of campus)
Foundation/non-profit sponsored trials:
   Per formal written policy of each
Industry-sponsored clinical trials:
   28%: at UNC or within 10 miles, 26%: remote (> 10 mile radius of campus)

F&A calculations for INDUSTRY Sponsored Clinical Trials are based on TOTAL DIRECT COSTS with the exception of the IRB Fee, which is an exclusion from the base. Adjacent rate applies to trials conducted within 10 mile radius of UNC (e.g., UNC Hospitals, Highgate Diabetes Clinic). Remote rate applies to trials conducted outside 10 mile radius of UNC Campus (e.g., Wake County Health Dept).

F&A calculations for Federally Sponsored Clinical Trials are based on MTDC. Modified total direct costs consists of all salaries and wages, fringe benefits, materials and supplies, services, travel and subgrants/subcontracts up to $25,000 of each subgrant/subcontract (regardless of period covered). Excluded: Equipment, capital expenditures, charges for patient care and tuition remission, rental costs of off-site facilities, scholarships and fellowships, portions of each subgrants/subcontracts exceeding $25,000. The IRB review fee is exempt from F&A (i.e., no overhead on this invoiced cost).

Non-profit funded trials: UNC generally accepts the foundation’s F&A rate policy. Please provide a copy of the foundation’s F&A policy along with the CTA or budget.

ITEMS REQUIRED WITH SUBMISSION OF ELECTRONIC INTERNAL PROCESSING FORM (e-IPF)
- FINAL sponsor-approved budget
- Internal Budget – list Principal Investigator and key personnel with salary and fringe
- Protocol – most recent version

SUBMISSION TO OCT: The initial draft agreement (i.e., CDA, CTA, or Amendment) must be sent to OCT accompanied by the appropriate Review Request Form (RRF). For new submissions, electronic copies of the protocol, sponsor’s draft consent form, and budget are also required. The RRFs can be found under QUICKLINKS at http://research.unc.edu/oct/.
Alternately, RRFs can be completed & submitted via CRMS (Clinical Research Management System) (http://tracs.unc.edu/clinical-research/clinical-research-management-system-crms.html).

For other frequently used sponsored research information, see also: http://research.unc.edu/offices/sponsored-research/resources/DATA_RES_OSR_INFOSHEET

TRIAL REGISTRY
Investigator-initiated studies must register within a qualifying public registry (e.g., ClinicalTrials.gov) prior to enrollment of the first subject in order to qualify for publication consideration in an ICMJE (International Committee of Medical Journal Editors) member journal. In addition, trials meeting the regulatory-defined meaning of an Applicable Clinical Trial (ACT) must register at ClinicalTrials.gov and report results. For more details, please see http://research.unc.edu/offices/clinical-trials/DATA_RES_OCT_REGISTERING or contact Monica Coudurier at m_coudurier@unc.edu or (919) 843-2333.

Updated: 2012Oct18