**Criteria for Appling Reduced Facilities and Administration**

**(F&A) Rate for Clinical Trials\*\***

An F&A (indirect cost) rate of 26% of total direct costs is applied to clinical trials that are performed by investigators at the University of Missouri-Kansas City. Total Direct Cost (TDC) is defined as all proposed direct costs minus expenditures for IRB fees, which is only charged on industry-funded clinical trials.

**NOTE:**

• The source of funding for the project is not the determining factor in qualifying for this rate.

• The research subjects must be studied under an IRB approved protocol.

• Commercially sponsored projects not meeting the criteria below will require the full UMKC research F&A rate.

• Studies meeting the criteria below that are funded by not-for-profit organizations may charge a rate as determined by negotiation between ORS and the sponsor agency.

For a trial to qualify for the reduced 26% F&A rate, *all* of the following criteria must be met (except in the special cases indicated):

• The study must be human clinical research.

• The study must occur in a clinical care area that meets all local and national standards for patient care.

• The research study budget must be appropriately charged for all expenses related to the study, including, but not limited to, personnel time and utilization of clinical care space.

• The research subjects cannot be charged for research-specific care.**\***

 **\***This criterion is not required if **ALL** of the following apply:

• The study involves a marketed drug or device or late phase New Chemical Entity, tested under Treatment Investigational New Drug or Compassionate Use protocols approved by the IRB.

• Use is judged by the investigator to be the only viable treatment option.

• Data are being collected.

• Application of the full F&A rate would make availability of the agent to the patient/subject cost-prohibitive.

Studies that do **NOT** meet the criteria for the 26% TDC F&A rate:

• Studies taking place in research laboratories or facilities that are not approved for clinical care, including studies involving human fluids, cells, or tissues.

• Studies involving only reviews of patient records

• Contracts solely for acquisition of human tissue, fluids, or cells to be stored (at UMKC or externally) for future research at UMKC or at an outside agency or institution.

**\*\*Source:** Adopted from materials developed by the UM-C School of Medicine Office of Medical Research and the UM-C Office of Sponsored Programs Administration

**Definition of Clinical Research\***

Clinical research is a component of medical and health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health. Clinical research embraces a continuum of studies involving interaction with patients, diagnostic clinical materials or data, or populations, in any of these categories:

1*.* disease mechanisms (etiopathogenesis)

2. bi-directional (translational) research

3. clinical knowledge, detection, diagnosis, and natural history of disease

4. therapeutic interventions including clinical trials of drugs, biologics, devices and

 instruments

5. prevention (primary and secondary) and health promotion

6. behavioral research

7. health services research, including outcomes, and cost-effectiveness

8. epidemiology

9. community-based and managed care-based research.

**\*Source:** Consensus Development Conference at the Graylyn Conference Center, Winston-Salem, North Carolina, November 20-22, 1998 as part of the Clinical Research Summit Project sponsored by the AAMC, AMA, and the Wake Forest University School of Medicine.