

NUMBER 12.1.07

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SECTION: ACADEMIC AFFAIRS

AREA: SPONSORED RESEARCH ADMINISTRATION

SUBJECT: THE COMMITTEE ON CLINICAL RESEARCH

PURPOSE

The purpose of this policy is to establish the duties and responsibilities of the UAMS Committee on Clinical Research (“CCR”).

SCOPE

This policy applies to all UAMS clinical research. UAMS Clinical Research is clinical research that involves any of the following:

1. UAMS faculty, staff or students;
2. UAMS owned assets (e.g. facilities, equipment and property);
3. Clinical services provided by UAMS; or
4. Research grants, contracts or agreements awarded to or subject to the control of UAMS.

Clinical Research is defined as any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge involving human subjects.

POLICY

The UAMS Committee on Clinical Research, with the assistance of its staff, is responsible for reviewing and approving all UAMS Clinical Research. The CCR review will include the following:

1. Whether there are sufficient funds and resources to cover all direct and indirect costs of the study.
2. Whether the protocol is proper in form, consistent with applicable regulations and is appropriate for consideration by the IRB.
3. Whether the informed consent is in proper form, consistent with applicable regulations and the protocol and is appropriate for consideration by the IRB.
4. A coverage analysis of the services to be provided in a clinical trial.
5. The regulatory requirements applicable to the study.
6. Whether the budget prepared by the principal investigator is accurate, is in accordance with UAMS billing policies and the amounts are sufficient to cover all costs itemized.
7. Whether any clinical trial agreement or other sponsor agreement for the clinical trial is consistent with University and UAMS policies, applicable state and federal law and appropriate to address the issues described herein above.
8. Whether the study is appropriately established and prepared to be conducted in compliance with all applicable Federal and State laws to include all Medicare, Medicaid and other federal programs’ billing regulations.

The CCR may disapprove any study where disapproval is in the best interest of UAMS.

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The UAMS Committee on Clinical Research's approval of a study is subject to the review and approval of the Office of the Vice Chancellor for Institutional Compliance.

PROCEDURES

The UAMS Committee on Clinical Research shall consist of the following members:

1. Dean of the College of Medicine, or her designee.
2. CFO of the Hospital, or his designee.
3. A faculty member with clinical research experience appointed by the Dean of the College of Nursing.
4. A faculty member with clinical research experience appointed by the Dean of the College of Pharmacy.
5. A physician with clinical and research experience in oncology appointed by the Chancellor in consultation with the Vice Chancellor of Academic Affairs and Research Administration and the Dean of the College of Medicine.
6. A faculty member serving as a member of the Research Council with clinical research experience appointed by the Chancellor.
7. No more than two physicians with experience in clinical research from different specialties reflecting areas of clinical research conducted at UAMS, appointed by the Chancellor in consultation with the Vice Chancellor of Academic Affairs and Research Administration and the Dean of the College of Medicine.

The Vice Chancellor for Institutional Compliance, the Director of the Office of Clinical Trials, the Research Compliance Officer, and the Hospital Compliance Officer are Ex-officio members of the committee.

The Chancellor shall appoint a Chairman and Vice Chairman from the Committee members.

The term of office for each member and ex-officio member identified by position is indefinite, appointed members serve an indefinite term at the pleasure of the appointing authority.

The UAMS Committee on Clinical Research will be supported by a permanent staff and additional staff provided by other departments. All staff shall report to the CCR through a Staff Director.

The UAMS Committee on Clinical Research shall adopt standard operating procedures for the reviews required by this policy.