Dissemination of Information through ClinicalTrials.gov

Title VIII of the Food and Drug Administration Amendment Act of 2007 (FDAAA) established legal requirements for sponsors and designated principal investigators responsible for certain clinical trials to register and report results information to ClinicalTrials.gov.

To comply with FDAAA, the National Institutes of Health (NIH) and the Center for Medicare and Medicaid Services (CMS) obliges grantees to follow registration and reporting requirements to qualify for funding. Further, the International Committee of Medical Journal Editors (ICMJE) established similar standards investigators must follow if they wish to publish in participating journals. This policy is intended to provide an organizational framework around and support to University investigators responsible for complying with regulation, grantor requirements and/or publication standards regarding registration and reporting.

The National Institutes of Health (NIH) has issued its policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov.

The University of Colorado, Denver, has created a support team to provide assistance in creating and maintaining records in the ClinicalTrials.gov system. This support team helps to assure compliance with the expectations of the University and with the NIH and the various regulatory and other bodies.

When conducting a study that meets the criteria for posting on ClinicalTrials.gov, the research must consider the appropriate regulations, for example:

Applicable clinical trials defined by Title VIII of the Food and Drug Administration Amendment Act of 2007 (FDAAA);

(B) Clinical trials funded, either in whole or in part, by the National Institutes of Health (NIH);

(C) Qualifying clinical trials which will render claims for items and services to the Center for Medicare and Medicaid Services (CMS)

(D) Clinical trials that meet the clinical trial definition of the International Committee of Medical Journal Editors (ICMJE) and, the results of which, the investigator plans to publish in a member journal. [NOTE: ICMJE accepts registration at registries other than ClinicalTrials.gov to meet their publication requirements.

It is the responsibility of the Principal Investigator to ensure registration and results reporting are completed and updated, and in the timeframes required, by FDAAA, NIH, CMS and/or ICMJE. The Clinical Research Support Center can and will provide support in order to meet these requirements.

Results reporting

It is the responsibility of the University of Colorado, Denver and the local PI to post the clinical study on ClinicalTrials.gov; the University of Colorado, Denver is listed as the “Sponsor” and the PI as the “record owner”. This assures that the University is better able to review and monitoring its postings.

RESULTS REPORTING
Principal investigators are responsible to report results of clinical trials registered at a publicly accessible registry, review the record for accuracy and ensure data-entry occurs within required time frames, as follows:

• FDAAA: Aggregate results and adverse event reporting on ClinicalTrials.gov must occur within 12 months of the Primary (endpoint) Completion Date;

• NIH: Aggregate results and adverse event reporting on ClinicalTrials.gov must occur within 12 months of the Primary (endpoint) Completion Date;

• CMS: If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur within 12 months of the Primary (endpoint) Completion Date. If the study does not qualify as a clinical trial under FDAAA or NIH, results reporting is voluntary.

• ICMJE: If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur within 12 months of the Primary (endpoint) Completion Date.

If the study does not qualify as a clinical trial under FDAAA or NIH, results reporting is voluntary. If a clinical trial is subject to registration requirements by more than one entity—FDAAA, NIH, CMS or ICMJE—it need only be registered once at ClinicalTrials.gov. Registration and results reporting must occur within the timeframe set by the applicable entities, whichever is sooner.

Detailed instructions for submission of study results are found on the ClinicalTrials.gov website at https://clinicaltrials.gov/ct2/manage-recs/how-report. Additionally, the Clinical Research Support Center provides hands on assistance and workshops regarding these requirements.

TRANSFER OF PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES During the course of a clinical trial, the PI may relocate to another institution or otherwise be unavailable to fulfill his/her role responsibilities as PI. Before leaving the University, the PI must work with the Department or Division Chief to ensure an orderly transition of his/her responsibilities to the new PI at the University or to initiate transfer of the registry account/record(s) and PI responsibilities to the new institution.